DECISION-MAKERS' CONCEPTUALIZATION AND FOSTERING OF COMMUNITY ENGAGEMENT FOR IMPROVED ADOPTION AND UPTAKE OF EXISTING AND EMERGING VACCINES IN INDIA

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To Baba, Ma, Babu, siblings Munai and Tukai, and the fur babies Popai and Rubae

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Tapati Dutta

DECISION-MAKERS' CONCEPTUALIZATION AND FOSTERING OF COMMUNITY ENGAGEMENT FOR IMPROVED ADOPTION AND UPTAKE OF EXISTING AND EMERGING VACCINES IN INDIA

India has introduced several vaccines and intensified decentralized vaccine delivery during the Decade of Vaccines (2010-2020). Alongside, there is high-level consensus that community engagement (CE) improves vaccination uptake and reduces burden of vaccine-preventable diseases. Despite progresses, existing evidence showcase lack of appropriate CE resulting in communities' resistance and backlashes leading to lower vaccination uptake. In addition, there is no evidence regarding 'what' vaccine decision-makers think regarding CE, and 'if' communities are engaged beyond individual decisions to vaccinate themselves and their children. This is problematic, because assuming a shared understanding of CE will only lead to erroneous assumptions about its value, or lack thereof.

This study uses three-stage concurrent and sequential qualitative methods to examine decision-makers' conceptualization of CE, and barriers and enablers to implement CE during the Decade of Vaccines. Twenty-five elite interviews among national-level vaccine decision-makers was triangulated with content analysis of 24 vaccine policy documents and researcher field notes. Participant follow-up meetings was convened from December 2018 to January 2019. Findings were reported using Social Ecological Model (SEM).

Decision-makers conceptualized communities variously: vaccine-eligible children, their parents, local-level vaccination influencers like health-workers, religious leaders, NGOs and

CBOs. The study identified broad spectrum of CE, expanding from the utilitarian-empowerment dichotomy. CE evolution ranged from house-to-house polio delivery to tailored interventions and information dissemination for vaccination among vaccine-eligible and resistant communities.

CE barriers exceeded enablers at all SEM levels. Policy-level enablers included political-will promoting social mobilization, whereas lack of a CE strategy was barrier. At organizational-level, cascade training of health-workers was considered a facilitator, whereas intrinsic power-relations within communities, and paternalistic attitude of authorities with communities were inhibitors. Partnerships with local organizations though acknowledged, their lack of institutionalization was a CE barrier at the organizational-level. At interpersonal-level, social-behavioral change communication and social-media messaging influenced communities' vaccination decisions. However, impromptu rumor management tactics and lack of strategies to replicate CE best practices hindered engagement. Participants recommended developing operational definition of CE in the vaccine arena.

Future studies should codify CE and its process-indicators in policy documents. Studies should map CE within intersectionalities to tailor strategies such that efficacious vaccines become effective vaccinations among communities.

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KEY THEMES

Community engagement, vaccination in India, evolution of community engagement, fostering of community engagement by vaccine decision-makers, barriers and enablers of community engagement, Social Ecological Model, Knowledge Flow Theory, elite interview, concurrent and sequential data collection and qualitative analysis.

CHAPTER 1

INTRODUCTION

Immunization Programs and Vaccine Delivery in India

Vaccines are lauded as one of the greatest public health interventions because they reduce the burden of infectious diseases. India has made tremendous progress during the aptly named 'Decade of Vaccines' (2010-2020) by introducing multiple new vaccines along with striving to increase access to new and underused vaccines in the country (Paul & Sahoo, 2015). Currently vaccine delivery in India is mandated through the Expanded Program on Immunization (EPI), which was rolled out in 1985 and later renamed as the Universal Immunization Program (UIP) (Bhatnagar et al. 2016). The UIP consists of vaccination for 12 diseases and available free of charge for all children and pregnant women in the country. These vaccines prevent tuberculosis, diphtheria, pertussis (whooping cough), tetanus, poliomyelitis, measles, hepatitis B, diarrhea, Japanese Encephalitis, rubella, pneumonia (Heamophilus Influenza Type B) and pneumococcal diseases (Pneumococcal Pneumonia and Meningitis) (Government of India, Ministry of Health and Family Welfare website; Travasso, 2015). To strengthen and invigorate the immunization program and achieve full immunization coverage at a rapid pace, the Government of India, in partnership with the World Health Organization (WHO), United Nations Children Education Fund (UNICEF), and other agencies launched Mission Indradhanush (MI) in December 2014 (NHP Admin, Ministry of Health and Family Welfare, June 18, 2018). MI includes interventions to increase full immunization coverage from 65% of children in 2013 to at least 90% in the next five years; targeting vaccinations for diphtheria,

whooping cough, tetanus, poliomyelitis, tuberculosis, measles, Hepatitis B and Haemophilus influenza Type B (PAHO 2013, Immunity Tales, 2015). The Indian Government has also introduced multiple new vaccines and increased access to new and underused vaccine in 201 districts where nearly 50% of all unvaccinated or partially vaccinated children of the country live. Of these districts, 82 (40.7%) are in just four states - Uttar Pradesh, Bihar, Madhya Pradesh and Rajasthan (Vaccine Confidence Project, 2017; Dey, Times of India, May 2016,). As part of the program, the Japanese encephalitis vaccine was launched in 2013, inactivated polio vaccine introduced in 2015, the rotavirus vaccine in 2016, measles-rubella vaccine in 2017, and twice during 2010 and 2016 there were attempts to introduce Human Papilloma Virus (HPV) through demonstration and pilot projects in five states of the country (Bagla, 2013, PATH, 2011). In addition, current discussions regarding the Pneumococcal, Dengue, and Meningitis vaccines highlight different stages in their development and introduction trajectory in the country (Paul and Sahoo, 2015; PMIIndia, 2014). For example, pneumococcal conjugate vaccine is supposed to be available in the States of Himachal Pradesh, Bihar, Uttar Pradesh, Madhya Pradesh and Rajasthan (PTI, 2016; The Hindu, May 2017). The dengue vaccine by Sanofi Pasteur is currently under review by policymakers, and another indigenous dengue vaccine developed by the International Centre for Genetic Engineering and Biotechnology (ICGEB) in collaboration with Sun Pharmaceutical Industries Limited is in the pre-clinical trial stage (Sharma, July 2017). The Meningococcal vaccine is recommended by the Indian Academy of Pediatrics (IAP) only for certain high-risk group of children, during outbreaks and international travelers (Indian Academy of Pediatrics website; Das, 2004).

Even with the recent significant changes in the strategic environment for immunization, including developments in new vaccines, increasing investments towards health system integration and decentralization, India fares very poorly in terms of vaccine utilization (Chatterjee et al. 2016; Laxminarayan and Ganguly, 2011). Recent numbers reveal that, only 65% children have been immunized through UIP in the first year of their life, with an annual increase in coverage averaging only by 1% in the past 5 years (Mathew, 2012; Patel & Nowalk 2009). The coverage is particularly sub-optimal for all basic vaccinations (BCG, measles, three doses each of diphtheria, pertussis and tetanus (DPT) and polio vaccines, excluding polio vaccines given at birth); with around 56% of partially immunized and un-immunized children under the country's UIP (Laxminarayan & Ganguly 2011). Again, a recent report by Tripathi in the Impatient Optimists (Bill and Melinda Gates Foundation (BMGF), 2015) notes that out of the 27 million vaccine eligible children born annually in the country, 8.9 million (or 32.9%) had received partial or no vaccination. Of these, 8.9 million, 7.2 million children were partially vaccinated for seven life-threatening diseases and 1.7 million (19.1% of all vaccine eligible children) were totally unreached leading to a huge burden of vaccine-preventable disease outbreaks (Tripathi, Impatient Optimists, April 10, 2015). Thus, understanding the barriers to vaccine utilization possibly having their bearing to CE, and rooted in social, cultural, religious and political contexts, is very pertinent (Goldstein et al., 2015; Obregan et al., 2009). Explanations offered for these outcomes include recurring incidents of community's skepticism and lack of vaccine support seen in vaccine resistance, recriminations and backlashes by the communities such as covert to overt vaccine resistance ranging from people closing their doors

and windows when they heard vaccinators approaching, to physical strife between vaccinators and communities (Larson, 2011).

The vaccine history of India is a story of complex, top-down policy and planning with decentralized delivery mechanisms. This means that the vaccine policy in India is guided by national policy, funded by the Ministry of Health and Family Welfare (MoHFW), and supported by the MoHFW Departments and country offices of international donor and technical organizations. The National Technical Advisory Group on Immunization in India (NTAGI) makes decisions concerning new vaccine introduction and immunization program improvement with inputs from other technical advisory members from the MoHFW, technical partners and non-profit organizations in the country (Chatterjee et al. 2016; Madhavi 2005).

One of the earliest examples of decentralized vaccine delivery was the Government of India Act of 1919, which called for devolved roles of local self-governments (a three-tier local government structure at village, intermediate or block and district-levels which self administrates the area) with the responsibility to provide health services, including smallpox vaccination. This approach had mixed results on vaccine uptake because of lack of funds for vaccinators (Bhattacharya et al. 2006). Currently, vaccination is delivered through the community-level health structures such as: Primary Health Centers (PHC) and Sub-Centers (SC) at the administrative Blocks and villages, which are the lowest level of governance in the country (Bajpai et.al. 2005). Vaccination outreach among the communities is done by multiple frontline healthcare providers. They include auxiliary nurse midwives (ANM) who provide

comprehensive primary care, including immunization services, and who reside at the Sub-Center of the designated catchment area; multi-purpose workers who live in the village and assist with vaccination delivery; Anganwadi workers (AWW); and community health workers (CHW). The latter two groups are responsible for mobilizing rural mothers to bring their children for vaccinations. Further, under the National Health Mission (NHM), there are Accredited Social Health Activists (ASHA) in the villages to encourage and facilitate full childhood immunization (International Institute for Population Sciences, 2007) (Figure 1).

[Figure 1]

Thus, in this devolved, decentralized vaccine delivery system, a core element widely endorsed is 'community engagement' (CE) - an ill-defined term - delimited to informing communities about vaccines (like eradication of a vaccine preventable disease); or informing communities about vaccination schedules, and/or escorting community members by the frontline healthcare providers for vaccinations (Sharma, et al. 2014; Tedrow et al. 2011; Rosenthal et al. 2010). Overall, the purpose appears to be utilitarian: to increase vaccination uptake.

CHAPTER 2

LITERATURE REVIEW

Community Engagement (CE) in Vaccine Literature

Both published and gray vaccine literature have emphasized the positive impact of community engagement (CE) in vaccination adoption and its utilization by the communities (Pramanik et al. 2018; Paterson et al., 2018). Global and country-level vaccine literature unanimously suggest early and ongoing CE for increased credibility of the informant/scientist/provider in the eyes of a potential adopter/user of vaccine, while also assisting the providers' comprehend and respond to implementation realities, develop product ownership and user readiness among the communities, leading to better vaccine outcomes (Rogers 1995; Grayson et al. 1999; Poff et al. 2003; Cooperrider et al. 2003; Becker 2005; Newman 2011; Larson, 2015). While policymakers, researchers and program personnel are increasingly acknowledging CE's virtue in vaccination utilization especially among the vulnerable populations, literature has critiqued on the varying levels of engagement perceived and practiced by decision-makers, and healthcare providers (Paterson et al. 2018.; Sarrami et al., 2014, Blanchard et al. 2013).

Literature on vaccines and CE have used different theoretical frameworks. For example, the Health Belief Model analyzes community vaccination decision-making (Sturm et al., 2005), public trust framework examines trust on vaccines and provisioning authorities (Gopichandran 2017), Social Network Framework addresses community's vaccine confidence-gap (Wonodi et al. 2012, Larson 2011), Knowledge Translation and Education (Shea et.al. 2009) and/or

Continuum of CE (International Association for Public Participation, 2014) promotes and sustains vaccine uptake interventions. Again, firstly, these studies are limited, and second, they mostly address an aspect of vaccine demand generation by communities, without any elaboration of CE processes, which assumingly had led to increased vaccination (Carnegie et al., 2017; Johri et al., 2015; Andersson et.al. 2009).

Summarizing vaccine literature, CE has been conceptualized as community-based tailored interventions, targeted mostly for high-risk or vulnerable populations, and undertaken by government or implementation organizations (Tedrow et. al, 2012; Walters et al. 2000). CE involves providing communities with adequate information about vaccine benefits and access, and supporting all aspects of specific vaccines and vaccination services (Doctor Et al. 2012). To accomplish this, CE entails home visits by health workers or mass-media messaging (Blanchard. et al. 2013; Tedrow et al. 2011). The outcome of CE is to increase community demand for and use of immunization services. Some studies suggest that CE would eventually help communities identify and address their own needs for specific health services (Blanchard. et al. 2013; Blankenship et al., 2008), or enable community-led monitoring and advocacy to address these health needs (Newman, 2011; WHO Technical Report). In these literatures, the emphasis is on community empowerment, collective advocacy, and ultimately community control (Ross et al. 2002; Bishop and Davis 2002). Again, some studies broadly define community/social mobilization as a downstream strategy to increase demand for or utilization of immunization services (Goldstein et al. 2015; Kochhar, et al. 2013). A recent evaluation in Ethiopia used CE as a strategy to implement a vaccine defaulter-tracing tool and a color-coded health calendar

(Paterson, Chantler, and Larson 2018). Again, a 2004 vaccine intervention study in Northern Nigeria explained CE as establishment of a network of thousands of community mobilizers who were engaged to increase awareness, understanding, acceptance and improve vaccine management of the polio vaccine after its boycott by the user community in 2003 (McArthur-Lloyd, 2016). Pramanik and colleagues' work in a state in India conduct randomized control trials whose results show that CE interventions addressed demand-side barriers while also mobilized the communities to advocate for better service delivery (Pramanik, et al., 2018). Again, in a previous study of African country plans for cervical cancer, 'community/social mobilization' mostly meant downstream efforts, which entailed community sensitization for cervical cancer prevention and control with very few plans conceptualizing it as involving and consulting the communities in the plan development processes (Dutta, Meyerson and Agley, 2018). In all, there are various overlapping terms used to express CE such as community involvement, public involvement, patient participation, consumer and community engagement, community mobilization, social mobilization, shared decision making, distributed leadership (Sarrami-Foroushani et al., 2010; Gronn 2002; Florin and Dixon, 2004). Others have suggested a 'continuum of CE' a progressive scale ranging from informing, consulting, involving, collaborating between government or organizations and the local communities, leading to empowering of these aforesaid communities (McArthur-Lloyd, et al. 2016; Bowen et al. 2010, Hart, 1997). Thus, even in this spectrum of conceptualizations of CE, ranging from government or other stakeholders giving information to the public regarding a particular service, to a genuine handovering of decision making power to the public, there seems to be an ambiguity in the definition and purpose of CE. Snape et.al.'s Delphi study found significant disagreement

between stakeholders on the purpose of CE in research as well as its justification on the grounds of ethics and patient empowerment (2014).

Program literature and evaluation studies in India have mostly used terms like 'community sensitization' when referring to CE-like concepts. This is defined as awareness of user-communities on the worth of immunization through community-based infotainment programs (Deutsch et al. 2017; Johri et al. 2015; Pandey, 2007). An infotainment or edutainment program is a knowledge change intervention combining education/information and entertainment. It is to be used in social venues, mostly measured as home visits by frontline healthcare workers. The purpose of these programs is to sensitize parents of infants, vaccine eligible adults, and communities about immunization for infants and pregnant women; follow up visits provided by ANMs, AWWs and CHWs to carry out first aid management of any minor side-effects resulting from the immunizations; other infotainment programs for vaccine awareness using mobile messaging and mass-media mechanisms; and occurrence of village council and *Rogi Kalyan Samity* translated as Patient Welfare Committee or village level Hospital Management Committee, meetings discussing any issues on immunization in the village (Adsul and Kar, 2013). Similarly, Lahariya et al.'s 2015 study conceptualized community mobilization as social marketing and other innovative communication strategies leading to increased vaccine utilization. Again, in these studies, there appears to be various understandings of 'community sensitization'; but all convey the conceptualization that CE-like activities are a form of information transfer about vaccines from government to communities (Garwick and Auger 2003; Wallerstein and Duran 2010). Most Vaccine utilization studies in India

have concentrated on the challenges like communities' lack of awareness ('did not feel the need', 'not knowing about the need' and 'not knowing where to go for vaccination' (Laxminarayan & Ganguly, 2011; Lahariya, 2015). Others have mentioned of myths and misconceptions on adverse events following immunization even when they might be unrelated to the vaccine (Bhatnagar et al., 2016) and mass-media and interpersonal communication impacting community's sensitization for vaccines (Gopichandran, 2017, Laxminarayan & Ganguly, 2011; Lahariya, 2015).

Most literature from India, as well as other developing countries, have either clearly expressed or implied one-way information transfer as CE-like activity, whereby the government and implementing organizations convey information to communities; rather than two-way participatory knowledge-flow (Perkin, 2009; Fraser, 2006). Evidence supports that this is occurring despite the fact that two-way knowledge flow facilitates capacity for critical thinking, decision making and action among communities (Dawson 2012).

Existing studies have suggested that sustained utilization of vaccines as a function of user's familiarity and knowledge of said technology, and credibility of the knowledge provider among the users (Steele 1989; Van Vliet and Gerber 1992). Studies from developing countries, where vaccine delivery is mostly decentralized like in India, suggest that groups and individuals in vaccine decision making positions should engage with communities early-on, during the planning stages of vaccine introduction, and sustain engagement throughout the implementation of vaccination programs to avoid vaccine implementation and acceptance

challenges (Paterson and Larson, 2012; Obregon and Waisbord, 2010). This suggests opportunities for two-way communication in CE.

Further, studies of CE suggest paternalistic, top-down information catering, merely manipulating or informing communities, which has led to lack of empowered immunization decisions by communities, increased anxieties about vaccine safety among communities, lack of credibility among communities on the vaccine delivery system (Shetty et al., 2010; Poore et.al., 1992) which in turn has resulted in lower vaccine uptake and in some cases even community-based vaccination backlash (Larson, et al. 2016; Centre for Public Impact, 2017).

Other key examples of knowledge flow are from the arena of coalition building like Himmelman's work which differentiates between networking, coordinating, cooperation and collaboration, and echoes with the two-way knowledge transfer process that 'collaboration' is the highest engagement process of exchanging information for mutual benefit, sharing resources, and enhancing the capacity of another to achieve a common purpose (2001). In similar work by Mohr et al. (1994) there is emphasis on quality sharing and communication for participatory rather than vertical relationships.

There is evidence that knowledge transfer interventions (whether conceptualized as CE or not), do not truly engage communities in an egalitarian way as they should be engaged. Li Hua's 2003 study suggests that the disparate levels of technological advancement between conveyers of information and potential adopter lowers the chance of successful knowledge

transfer (2003). These differences have been conceptualized as a 'two-community' problem; meaning that socio-cultural differences between knowledge providers and users are barriers to engagement (Caplan, 1979; Cullen, 1990; Baskerville, 1997; Walters, 1998; Saywell and Cotton 1999; Cullen et al. 2001; Kinzig 2001). Even when there is two-way communication, studies have suggested that differential power dynamics can serve to 'co-opt and capture' community input rather than accord them independent vitality (Head, 2007). Again, the study of African national cervical cancer prevention plans found a related concern of token involvement of communities, who were either referred to as 'cancer survivors' or 'patients' (Dutta, Meyerson, and Agley 2018).

Such evidence has led to gradual shifting of emphasis away from a top-down approach to CE and towards building institutional bridges between governmental leaders and citizenry. In some cases, interest has focused on consultative CE to help develop vaccine policies (Vigoda 2002; Lovan et al 2004; Kochhar et.al, 2013). Expressions of this shifts include the formation of advisory groups at the global level such as the Working Group for Vaccine Hesitancy under the WHO Strategic Advisory Group of Experts on Immunization (SAGE) (Dubé, et.al., 2014); and the Practice-based Research Networks of the Agency for Healthcare Research and Quality (AHRQ) (Wallerstein & Duran, 2010) which have been considered as CE. Similarly, whose second Strategic Objective by the Global Vaccine Action Plan (GVAP) expressed the belief that communities need to be more than passive recipients of immunization services (WHO, 2013). Further, there are recommendations that emphasize listening to community concerns, understanding public perceptions to inform risk communication, and incorporating community

perspectives in planning vaccine policies and programs (Larson and Watson, 2011). Similarly the Indian Academy of Pediatrics (IAP) mentions, *"Involvement of community should be solicited"* in their Recommendations for Vaccine Associated Paralytic Polio (IAP website) and the MI emphasizes to *"generate awareness and demand for the immunization services through a much needed community-based communication strategy and social mobilization activities to enhance the participation of the community in the routine program of immunization through the mass-media, mid-media, interpersonal communication and school, youth networks, and corporate*" (Mission Indradhanush, Operational Guidelines, 2015). In 2001, The Vaccine Policy of India identified the need to conduct operational research to gauge the perceptions of the target community about immunizations towards developing community-responsive communication and advocacy strategy (Vaccine Policy of India, 2011). This conceptualization is more akin to market research to guide information flow.

Thus, India's need for a more engaged and dynamic conceptualization and practice of CE is warranted, given its substantial history of community backlash against different vaccines, primarily due to this top-down approach in vaccine planning and delivery. The earliest example occurred in 1850 over smallpox vaccine. Here, some Hindus resisted the smallpox vaccination because of religious incompatibility issues: the material used in cowpox vaccines was lymph from the cow. This was not acceptable, because cows are considered sacred by the Hindus (Bhattacharya et.al. 2006). In this example, Basu argues that this and the lack of tailored strategies to reach the hard-to-reach populations resulted in low smallpox vaccine uptake and coverage, with associated outbreaks reported even after five years of its roll out (Basu, 2006).

But this was likely not the result of strategic tailoring, per se, but a lack of initial CE about the strategy used in the first place. Basu and others arguing for strategy-tailoring issues are likely pointing to a more central issue of CE in the initial design of the strategy in the first place (Basu and Mittal, 2011).

Vaccine uptake and acceptance issues have continued in the current era and are usually expressed post vaccine program implementation. For example, in 2010, the Government of India suspended HPV vaccination demonstration projects due to public concern about vaccine safety and conflicts of interest (Nigam 2014; Sarojini et.al, 2010). Community groups expressed concerns about pharmaco-governance, or pharmaceutical companies overreaching into the priorities of national governments, pushing vaccine onto an unsuspecting public (Larson & Watson, 2011). In the HPV case, it is not yet understood whether and how the government engaged communities prior to the implementation of the HPV pilot studies. It was argued at a press conference in 2010, that there was no engagement with the communities selected by the government and NGO implementers prior to pilot implementation (Larson et al., 2016; Bagla 2013, Larkin, 2007).

As recently as 2017, rumors shared via social media platforms of WhatsApp and Facebook fueled a mix of political conspiracy and safety concerns about the measles-rubella vaccine which brought down the immunization rates of otherwise better performing states like Tamil Nadu in India, by almost 10% (Sharma, Hindustan Times, January 2017). Here, however, Nichter and colleagues presumed an information-flow problem as examples of community's

misinformation about vaccines, particularly among conservative Muslim and Hindu groups who linked immunization programs with hidden political agendas to selectively use anti-fertility agents among specific communities (1995). It may, however, be the case that here too, CE prior to vaccine program initiation could have informed information flow and programming. To my knowledge, no study has made this observation.

Literature Gap in Understanding CE in the Vaccination Arena

Notably, while the huge enthusiasm for CE through bi-directional knowledge sharing and transfer has been well expressed, there is a paucity of research about precisely what CE means, what engagement methods might be for effective knowledge-flow, and the necessary policy capacity to engage the communities. A key challenge to this is assuming a shared understanding of CE, which lacks a clear definition of what it is and how to measure it. Bell and Morse indicate that this might lead only to erroneous assumptions about its value, or lack thereof (2003). One of the major reasons for this literature gap could be because of the complexity in unbundling the concept of CE particularly in countries like India (Larson, 2011), as well as developing CE indicators (USAID, Health Communication Capacity Collaborative, 2017). Again, there are several unexplored areas when assessing the true nature of participatory governance, as to whether expressions of enhanced participation is due to the growing influence of the communities or whether these processes are largely the result of state-directed outsourcing and state-controlled devolution (Foreman, 2002; Weber, 2003; Rhodes, 2003). Many authors are also unclear of the robustness and independent strength of CE when it is largely at the discretion of the government and is largely shaped and subsidized by the latter

(Head and Ryan 2003; Head 2007). Despite these challenges, attempts must be made to advance the understanding of how best the communities are being engaged for vaccination uptake in India and what has been the mandates, resources and preparedness of the government and vaccine decision-makers in doing so.

AIMS

This dissertation research thus proposes to understand how vaccine decision-makers (individuals those with vaccine policy and programmatic decision-making positions at the national-level) - conceptualize CE and foster it. In addition, this research will identify the facilitators and barriers in implementing CE in the vaccine space of India.

Research protocol was approved as Exempt by the Indiana University Institutional Review Board (IRB) (Protocol number 1710654732A001) (Appendix C).

The study advances the following research aims:

1. To examine and characterize the conceptualization of CE for vaccine introduction, uptake and adoption by national-level stakeholders with vaccine policy standing in India, particularly during 2010 to current period encompassing the Decade of Vaccines.

2. To explore barriers and enablers to community engagement for effective introduction and increased uptake of vaccines in India during the 'Decade of Vaccines' (2010-2020).

These aims will help to identify opportunities and lead to future studies of how conceptualizations of CE affect vaccine confidence and uptake among the targeted communities in India. This dissertation will be significant for three reasons. First, while the rhetoric surrounding CE and participatory knowledge transfer is momentous, few studies have

drawn on preferences of those with a vaccine policy standing to adopt and advance CE (Brukardt, et al. 2004). Second, little research has been conducted to explore if there has been any transition from a paternalistic model to a consultative model of CE for vaccine introduction and its uptake during the Decade of Vaccines in India. Third, the study findings are time sensitive and will inform current CE strategies for new and emerging vaccines in India, to stimulate and sustain vaccination decisions, improve vaccine confidence and reduce the scope of vaccination backlash. These aims will help to identify opportunities and lead to future studies of how conceptualizations of CE affect vaccine confidence and uptake among the targeted communities in India.

CHAPTER 3

METHODOLOGY

As expressed earlier, this dissertation advances the following research aims:

1. To identify and characterize the conceptualization of CE for vaccine introduction, uptake and adoption by national-level stakeholders with vaccine policy standing in India.

2. To explore barriers and enablers to CE for effective introduction and increased uptake of vaccines in India during the 'Decade of Vaccines' (2010-2020).

Study Design

Examining the study aims was informed by Schutz's social phenomenology both as a philosophical framework and a methodology (2012), where interpretive research throughout the research process (Koch 1994) was used to demonstrate credibility or trustworthiness. A three-stage concurrent and sequential method of data gathering and qualitative analysis was used: (1) scoping archival review of vaccine policy documents, (2) key informant interviews with vaccine decision-makers in India, and (3) member check-in follow-up meetings with study participants and their teams (Figure 2). The study design allowed each concurrent stage to evolve and advance mutually from one another.

Schutz's postulate of adequacy resonates with this interactive and iterative process of key informant interviews, document review and member check-in follow-up meetings. It helped

to validate and confirm findings with participants (Cutcliffe & McKenna, 2002). In addition, presentation made by the primary researcher (Dutta) of the initial data interpretation in the follow-up meetings ensured an accurate summary and some further recommendations by participants and their teams. This process allowed for consistency in the method though could not provide multiple interpretations and examples of CE postulated by decision-makers from different fields. When using this method for another study, the data coding could involve other themes being developed by experts from other fields (Sandelowski, 2002).

[Figure 2]

Rationale for this approach

This multi-stage method facilitated understanding the vaccine decision-makers' conceptualization and evolution of CE, advance continued search of vaccine policy documents, and facilitated exploring any new CE themes and categories like the identification of a CE spectrum rather than a dichotomous 'no community engagement' and 'high community engagement' (Van Maanen, 1979).

For the purpose of this study, vaccine decision-makers are those people who hold positions of authority, which influenced policy development or implementation (plans, programs) from the national-level.

Vaccine policy documents were included to provide an understanding of institutional orientation toward CE. Such documents will indicate whether there is evidence of CE's

consideration, evidence of how existing CE priorities reflect leadership priorities, and provide insight into institutional conceptualizations of CE.

Data Gathering

Planning the Key Informant Interviews (KIIs) and Archival Document Reviews

A semi-structured interview guide was used to facilitate the key informant interviews and archival document reviews. The guide was developed based on an interview protocol used by Project Muse which explored how public research universities are adopting a two-way interactive model of engagement on their campuses are the barriers and enablers that either inhibit or promote engagement in these institutions (Weerts, D. J., and Sandmann, 2008).

Study guide sections included the following: (1) organizational conceptualization, policy, practice, history around CE including conceptualization of 'community' and 'engagement', (2) organizational arrangement and resources for CE, (3) leadership support for CE, (4) coordination, capacity building and local partnerships to support and advance CE strategies, (5) barriers and facilitators of CE, and (6) CE and social mobilization delivery strategies, innovations and evidence building. The interview guide is in Appendix D.1. Initially it was planned that the duration of an interview would be 30 minutes.

Review of vaccine policy documents

A scoping review of the overall content of the vaccine policy documents was conducted, due to the diversity of the archival documents, broad scope of CE, limited time,

and no earlier national-level review on this topic (Arksey, 2005). The work was guided by scoping reviews done by Thulien (2014) and Williams-Brennan et al. (2012). Thulien conducted scoping review to determine gaps in current knowledge on cervical cancer screening for sex trade workers. Williams-Brennan and colleagues analyzed interaction among different social determinants of health and their impact on cervical screening among women in low and middle-income countries. This dissertation also referred to the African Palliative Care Association's (APCA) scoping review on palliative care policy development in each African country (Rhee et al., 2014). Elements in these studies resonated with this study because these were conducted at the national or continental-levels, entailed reviewing diverse gray literature, analyzed aspects (like cervical screening) which, though aspired by policymakers were compromised given the resource constraints and health governance related issues of Africa. However, typical of biomedical and epidemiological research, these studies explored single socio-demographic variables affecting cervical cancer screening, whereas this dissertation research has identified CE at all levels of Social Ecological Framework and has additionally proposed intersectionality approach for a richer understanding of CE.

Inclusion, Recruitment, and Conduct of KIIs

For the vaccine policy documents, initial Boolean internet search was conducted between November and December 2017 using words like 'vaccine' AND 'policy' OR 'guideline' AND 'India' which helped to identify 20 policy documents. Thereafter when the study aims were shared with the abovementioned study participants, they recommended more documents, which were added to the list. All the documents were available online in the

website of Ministry of Health and Family Welfare (MoHFW), Immunization Technical Support Unit (ITSU), National Technical Advisory Group on Immunization (NTAGI), country offices of the World Health Organization (WHO), United Nations International Children's Emergency Fund (UNICEF), and CORE Group Polio Project (CGPP). In most cases, the Communication personnel helped the researcher with the links or provided a hard copy of the policy documents. Twenty-four vaccine policy documents in English language, which were available online were included in this study and were reviewed.

Vaccine decision-makers were purposively selected for their policy and program management experience and an initial list of 30 potential participants was created. Because of the position of authority, along with their publicly available contact information, identification of the vaccine decision-makers was not too difficult. Twenty-eight participants were selected through snowballing process based on informal discussions and networking by me. Approaching them became comparatively easier because of my earlier work on CE with some of these vaccine decision-makers in India. Two had to be excluded from the list because one did not have a physical office in India, and another could not be contacted. First, an email was sent to all the 28 decision-makers in December 2017 explaining the study information and requesting an invitation for an interview (Sample of the email highlighting study purpose and requesting study participations can be found in Appendix D.2). In case of no responses from the study respondents or their office, the first follow up emails were sent in early January 2018 after around ten working days. In most cases, once the decision-maker consented via email to

participate in the study, follow up phone calls and emails were sent to their offices requesting an interview date between 12-15 days after the initial invitation.

For most respondents two emails followed by a call yielded response. However, for representatives at the Ministry, initial email by me, followed by an introductory/reference phone call by another contemporary in the Government/donor/technical organization facilitated accessing the potential interview participants and recruiting them. Twenty-five vaccine decision-makers participated in the one-on-one interviews. Follow up calls were made to their offices to finalize on the interview date. Due to the ongoing Winter session of the Indian Parliament then, the media critiquing regarding the pilot of HPV vaccines, and the rollout of measles-rubella (M-R) vaccines, most of the decision-makers were very busy (Rao and Govindarajan; Feb 2017; Khan, May, 2016; Jayachandran and Raman, August 2018). Thus, it would often take more flexibility of time on the lead researcher's (Dutta) part to finalize the interviews, at times conducting them at unconventional times, like early mornings or on national holidays. In addition, politicized sensitivities had to be acknowledged and caution was exercised while tailoring questions on aspects like 'CE and preparedness for HPV vaccine introduction in India?' Details of the process of inclusion of study participants and vaccine policy documents is explained in Figure 3.

[Figure 3]

The key informant interviews were conducted by Dutta in-person during December 2017 to February 2018. All the interviews were conducted in English, in the offices of the decision-makers. The offices of these decision-makers were located in New Delhi the national capital of India or the National Capital Region, which constitutes of places around the city of New Delhi. The interviews lasted approximately 45 minutes to an hour. Verbal informed consent was obtained from all participants prior to conducting and recording the interviews.

Conducting convening follow up meetings

The study also involved convening participants as a group in December 2018 to verify the findings from the key informant interviews. This was decided because it would give a chance to confirm the completeness of archives included and seek clarifications from interviews, if any. The plan was to conduct further review and analysis based on the outcomes of this meeting. Emails requesting for this meeting were sent to all the participants during the first week of December 2018. Except one person at the Ministry, and another heading a multi-partner project, all the participants expressed keenness and participated in the convening meeting. Additionally, participants from the technical bodies of the Ministry, NGOs, and donor organizations, invited other colleagues of their organization or Department to join in the discussion. Three participants who could not be present during the convening meeting invited Dutta for one-on-one meetings at their respective offices during January 2019.

Theoretical Framework and Measurement

This study is guided by the hybrid conceptual frameworks of Knowledge Flow Theory (KFT) (Weerts, 2007a, 2007b) and the Social Ecological Model (SEM), to explore the framing and fostering of CE by those having a vaccine policy standing in India.

It was initially anticipated that the realms of CE measurement in the KFT framework (Carnegie Community Engagement Classification) would guide tailoring CE categories in the study. The Holland Matrix of the KFT provides a structured framework for an academic institution to assess its 'state of preparedness' for engagement and interaction with communities. The matrix offers a framework for measuring university capacity and preparedness to 'engage' with communities in shared work that is of mutual benefit (contributes to teaching, learning and research outcomes, while also collaborating with external communities seeking improvement in community outcomes) (Holland, 2001). Partnership and reciprocity are key aspects of this form of CE. The instrument asks applicants to describe how they seek feedback from communities on several levels.

Examples of questions in the KFT framework were:

(1) ‘Does the executive leadership of the institution explicitly promote community engagement as a priority?’

(2) ‘Does the institution have a campus-wide coordinating infrastructure to support and advance community engagement?’

(3) ‘Is community engagement defined and planned for in the strategic plans of the institution?’

An example of the KFT themes is cited in Table 1.

[Table 1]

The hypothesis of KFT is that, knowledge creation, such as in the case of vaccine policy or programing, is an evolving process and occurs in the context of a community. CE and community-level collaborations, are thus both, knowledge building processes and a developmental outcome, which emerges from a series of ongoing, informal and formal relationships between the communities and the policy-level decision-makers (Håkansson, 1990; Von Hippel, 1988). KFT challenges knowledge hierarchies, such as expressed through top-down vaccine policy or programming, and reflects the work of Nyamnjoh who considers everyday life of social spaces as bona fide research sites [which] entail, 'taking the popular, the historical and the ethnographic seriously, and emphasizing interdependence and conviviality' (Nyamnjoh, 2015).

A challenge was that there is limited work using KFT, and as such, required primary reliance on work by Hutchinson & Huberman (1993), National Center for the Dissemination of Disability Research, (1996), Weerts, and Sandmann (2008). These studies using KFT have focused on the 'knowledge flow space' and its 'directionality' in higher education academic settings studying academic-community partnerships to distinguish between one-way or top-down versus two-way or bi-directional knowledge transfer approaches (Weerts, 2007a, 2007b). By understanding this directionality of

knowledge, KFT helps to understand whether community engagement has been participatory versus top-down and identifies barriers to build productive relationships between universities and other external stakeholders like community partners. Using knowledge flow as a key aspect of CE means reciprocity in interaction and knowledge transactions between communities and the government; local partnerships acting as a sounding board to the government in sharing community's vaccine concerns; and participating in vaccine planning.

This dissertation followed the philosophy of several reformist and developmental orientations to reiterate the critical importance of bi-directional knowledge sharing and co-learning as opposed to unidirectional flow of knowledge in vaccine policies and programs in India, the latter being termed as 'bad outreach' by some authors (Zandvliet and Anderson, 2009). For instance, seminal work by Foucault has already provided a theoretical grounding on the intrinsic interconnectivity of knowledge and power, and how knowledge is produced within power relations which influences the broader discourses and that the power-relations of discourses are deterministic to what will be known (Ball, 2013; Foucault, 1980; Dimitriadis, 2006). This is close to Ostrom's work who proposed 'knowledge co-production' as between decision-makers and the communities (1996).

It was ideated that the Holland Matrix of KFT will measure institutional intent in bi-directional knowledge transfer. This matrix has been used in other KFT studies, though not very widely, and measures CE as the collaboration between institutions of higher education and

their larger communities (local, regional/state, national, global) for the mutually beneficial exchange of knowledge and resources in a context of partnership and reciprocity (Carnegie Foundation for Advancement of Teaching, 2006; Holland 2001).

Initially though KFT was chosen, due to the inherent limitations of the matrix in looking at 'vaccine decision-makers and 'communities' as conglomerate wholes, interacting in two-way top-down or bottom-up communication, SEM model was laid. The lens of knowledge transfer was used to analyze CE and vaccine related knowledge transaction. The evolution of the use of the theoretical framework is explained in the following sections.

Limitations in the Knowledge Flow Theoretical (KFT) Framework

This study focused on a different sense of CE as compared with the KFT framework. The KFT's definition focused on institutions and their relationship with various publics, whereas the conceptualization of CE involved in this dissertation entailed decision-makers' engagement of community members as self-determining actors in ways that led their own understanding and uptake of strategies and actions to improve their vaccination decisions. In this context, there is a subtle but important distinction between these two views of CE. In the Holland Matrix the interaction between university and community was more one-way rather than reciprocal, though it was not very clear.

For example, Zhuge (2006a. 2002) defined Knowledge Flow as sharing and processing of knowledge among individuals; differing based on the direction, content

and carrier of the knowledge. Here, the assumption is that knowledge is diffused from those who are positioned 'higher' than the community such as formal authorities. Some Knowledge Flow theorists also suggest partnerships through 'Knowledge Nodes', which is a single persons or groups who begin a learning path starting from a specialty – whether functional specialization, specialization of product, of process, that are linked by some kind of complementarity, so as there are opportunities to generate value by exchanging or pooling inputs between the senders and the recipients (Zhuge, 2002; Zhuge, 2006b). Here, the flow of knowledge is identified either resulting from a trigger of a source which is known as push strategy or a knowledge request made by the recipient, known as the pull strategy (Jarrahi and Kangavari, 2012; Zhuge, 2006a). In this case, there is an unsubstantiated assumption that biomedical knowledge, once reached and reinterpreted by the communities will be appropriated and accepted by the community and become part of the local belief system (Geissler & Pool, 2006).

The belief was that this framework and related philosophy overlooks the possibility that knowledge may also be in conflict with the traditional existing knowledge of the community (Bisht & Coutinho, 2000; Bastien 1995). In the case of immunization, as earlier studies have highlighted, even when communities come to accept vaccination, they do not necessarily do so with the biomedical understanding of vaccines and immunity they provide (Bisht & Coutinho, 2000). Also, knowledge exists at many levels in organizations, and with the increasingly online sharing mechanisms (Hara, Shachaf, & Hew, 2010) there are increasing tendencies among communities not to rely on experts to gain scientific knowledge (Hara and Sanfilippo, 2015).

The approach also seemed ill-equipped to address the plethora of political, social and economic conditions and grounds for social resistance to repetitive top-down information sharing for immunization.

Laying CE and KFT in the Socio-Ecological Model (SEM)

Following this line, it was decided that the existing ready-to-use KFT might be an over-simplistic depiction of analyzing the tenets of CE in the vaccine arena, whose inquiry involves complicated, and multiplicity of interacting factors. Therefore, a hybrid of KFT and Socio-Ecological Model (SEM) adapted to analyze differential power between those communicating and those receiving information was used. This seemed the most appropriate because, community engagement is a complex process, expressed at multiple levels, and entails behavior change interventions, establishment and maintenance of partnerships among diverse community groups, which perhaps is encoded in policy (e.g., educational, regulatory, economic).

The SEM has been used extensively in the field in health promotion, both as a tool to elucidate its etiology, as well as developing interventions, and measuring their efficacy. One theoretical basis for SEM is visualizing individuals and communities in concentric layers, where individuals are embedded within communities, communities form social networks, which in turn are within institutions, and are impacted by policies (Kumar, et al. 2012). Stokols and colleagues argued that it is the interventions at multiple social ecological levels because that leverages contextual and cultural knowledge, practices, and resources of all individuals and

organizations involved, while also contributing to sustainability of the interventions (1996). McElfish et al. perceived SEM as a facilitating tool to allow interventions at distal contextual levels that target across multiple levels simultaneously to leverage both, environmental and behavioral effects (2016). The social ecological paradigm for health promotion extends these notions by providing a set of conceptual and methodological principles, drawn largely from systems theory advocating for interventions at different levels for widespread influence (Stokols, 2000).

The vaccine and SEM literature have expressed communities' vaccine decision-making as a function of their perception of individual risk, the prevalence of vaccine uptake in their area, their perceptions of susceptibility of contracting the disease, as well as if they are encouraged to get the vaccine by their healthcare providers, and whether federal healthcare policies favor their access to affordable vaccines (Kolff, 2018; Nambe, Hal and Kamden, 2016; Kumar, et al. 2012). In his work Kumar et al. used SEM to demonstrate that factors on all levels of the SEM influenced whether communities received the H1N1 influenza vaccine and recommended interventions targeting multiple levels than targeting specific levels. Similarly, UNICEF Communication for Development (C4D) supports combination of interventions at all levels and corresponding C4D approaches for every SEM level like: Behavior change communication, social mobilization (including strengthening an enabling media and communication), and social change communication and advocacy that produces program synergies for positive change within a social system (UNICEF, (C4D)). Other spheres of biomedical prevention, like the North Carolina Breast Cancer Screening Program collected

process data about environmental, organizational, program and individual characteristics (Viadro et al., 1997). CDC uses SEM by identifying high-impact 'leverage points' in resource-limited settings noting that multi-level systems approach using combination of interventions at all levels optimizes resources and likely has a higher chance of success (Proctor et al. 2004).

While SEM has been extensively used, there is limited evidence assessing the distribution of CE interventions leading to vaccination and health benefits by socio-economic strata. This becomes more critical in the context that GVAP lists equity as one of its six guiding principles (Brearley et al., 2013). This study does this with a paradigm shift, away from studying focused interventions aimed primarily at changing individuals' health behavior, to more comprehensive ecological aspects of CE, which examines the interdependencies between, political, organizational, community, and individual-levels. This, to some extent is able to address what Burke et al. have pointed out as 'reciprocal determinism' between various levels of the SEM impacting behavior which may involve interactions between levels over time (2009). The study while indicating engagement efforts being carried out at various levels, also hopes to highlight any particular conjunction of interventions at the interpersonal, institutional, organizational, community, and policy levels which were found to be most effective.

Further, there seems to be a tendency of failing to apply the whole SEM model consistently in the whole ecological canvas of CE, and a rather narrowly concentrating at vaccination uptake, or a particular intervention. We argue that the SEM can be a useful analytical platform to examine CE across all populations, assess enablers and barriers of CE at

each level, and how interaction occurs between levels, which may help improve the impact of interventions, and vaccination uptake. This will help to clarify and assess the magnitude of CE factors for immunization and enable recommending policies and programs to address them in the current setting.

That said, vaccination decisions are shaped by past experience such as witnessing side effects or bearing any misunderstanding regarding vaccinations based on the collective memory of their group heard over the life span, rather than one's own perception and characteristics. A limitation of using this theoretical framework is that while it adds to the one-dimensional continuum (from minimal involvement to active engagement), and the two-dimensional vaccine information flow process between communities and the authorities, it has not analyzed CE in a three-dimensional perspective of engagement processes, knowledge co-production, and time.

The Social Ecological Model (SEM) conceptualizes that individuals' vaccination outcomes is influenced by the dynamic policy, community, organizational, interpersonal, and individual factors (Kumar et al., 2012; Kolff et al., 2018; Nambe, Hal and Kamden, 2016; Baral et al., 2013). For example, the policy-level factors includes policies and regulations affecting communities and the institutions, the community-level factors are incumbent of the relationship among different institutions within communities, the organizational-level factors constitutes institutional organization and management, the interpersonal-level factors include interactions of individuals with families, peers, neighbors, and healthcare workers and the individual-level

factors include vaccine related beliefs, values, and other individual factors (Crosby, Salazar, & Decremented, 2013; Oku, 2016; Spiegel 2005). Considering that the SEM theory has been earlier used to understand vaccination uptake (Kumar, 2012; Nambe, Hal, & Kamden, 2016), a deductive approach was used to identify recurring and emerging themes (Hsieh et al. 2005; Elo and Kyngäs 2008).

Measurements

Data from interviews, archival documents and field notes were categorized by SEM levels as follows (Table 2):

(1) Policy-level factors include written evidence of CE in policies, strategic plans, regulations, and mention of incorporation of CE in vaccination campaigns, examples of political will ensuring resources for CE or incorporation of CE during disease outbreaks, which influenced positive vaccination decision among communities.

(2) Community-level factors include power-structures in the society like structural barriers related to class, caste, gender, rural versus urban divide, and community's lack of trust expressed in incidents where communities have negotiated, bargained and/or strategized with the vaccine providing people/organization – like *'build the road then we will take the vaccines'* or critically questioned the intent of the vaccinators like *'what must be the plot of the Government to vaccinate'*, which has affected communities' trust on the vaccination providing systems and thus impacted the vaccination rates.

(3) Organizational-level factors means formal or informal partnerships between national and local stakeholders like religious leaders, clubs like Rotary and Lions, women's self-help groups, youth groups like NSS, NCC, NYK, who undergo training by the MoHFW, UNICEF and WHO, and in turn, as local champions influence positive vaccination decision among communities. Engagement with these local role models or vaccine champions is distinctly different from celebrity engagement, which is vaccination sensitization of communities through mass-media done by a famous personality.

(4) Interpersonal-level factors included issues around Inter Personal Communication (IPC) and Social Behavior Change Communication (SBCC) on which healthcare workers are trained to thereafter counsel communities for vaccination.

(5) Individual-factors consisted of any examples of direct communication between decision-makers and communities addressing vaccine concerns reflecting the latter's belief and perspectives of meaningfully engaging with communities which affected community's decision to vaccinate themselves or their children. It also includes management of vaccine related myths, rumors, and misinformation among communities by decision-makers.

[Table 2]

Coding

First, all the interviews were audio taped and transcribed verbatim by me after excluding "ums" and "ahs." Researcher field notes taken during both, the archival document review and during the process of interview, and convening meetings and were included as a memo to the respective interviews or meetings. Field notes were based on the manifested and latent expressions of the study participants and helped my interpretive analysis that is concerned with the response as well as what may have been inferred or implied during the interview. Based on the transcribed raw data collected on the CE focal areas, and my field notes, a chronological meaning making was done describing how the CE component came about, key collaborators who were/are involved, and the major milestones. Study participants were requested to review their transcribed files, but due to lack of time the summary with the respective participants had to be reconfirmed.

An *a priori* deductive framework, which complemented the research questions by allowing the CE tenets to be integral to the process of organizing text for a deductive thematic analysis while allowing themes to emerge direct from the data (Fereday and Muir-Cochrane 2006). It helped develop the coding constructs that defined the components as well as barriers and facilitators of CE. Thereafter, two researchers and I reviewed five transcribed interviews and two policy documents independently in November 2017 and coded these. Inter-coder reliability (Kappa) was established with >90% consensus among raters through repeated readings and re-readings of the interviews and documents and consensus meeting discussions. This was an iterative procedure (Glaser and Strauss, 2017) that involved moving between the

summaries, existing theory, and the interview data, particularly during the integration of the interview data with the archival documents. The concepts identified were reintegrated into themes, which provided the structure for the results. This led to a form of pattern recognition, with emerging themes/nodes becoming the categories for analysis (Fereday and Muir-Cochrane, 2006). For example, the study characterized different CE to the extent to which they might have generated new practices, strengthened adoption of vaccines or built sustainable and distinctive capacities. Thereafter, these categories were refined by tracing patterns and consistencies (Mintzberg, 1979): the interviews were scrutinized and initial ideas elaborated as additional evidence. The analysis continued with this interplay between the data and the emerging patterns until the patterns were refined into adequate conceptual categories (Bailyn, 1977; Eisenhardt, 1989).

The final coding instrument consisted of seven themes and 42 sub codes (Table 3). This final coding instrument was used to code the data of the interviews and policy documents. NVivo 12 (QSR International, Melbourne, Australia) software was used for line-by-line, open and axial coding, with openness to new themes that emerged.

The first step was to analyze each interview and policy document to identify key CE fostering mechanisms and barriers. Thereafter CE enablers and barriers for vaccination were classified into all the SEM levels: policy-level, community-level, organizational-level, interpersonal-level, and individual-level factors and reported as exemplar quotes from interviews and content of the policy documents. Constant comparison was used to highlight

similarities and/or differences between aspects of CE mentioned during the interviews but not in the policy documents or vice versa. Finally, the transcribed data from the archival review, analyzed interviews, and field notes were triangulated for validation, address completeness, convergence, and dissonance of key themes.

[Table 3]

Restatement /Clarity about the Methods Used for the Following 'Findings' Chapters

The first findings chapter (Chapter 4 in this dissertation) of my thesis titled '**Vaccine decision-makers' conceptualization and fostering of community engagement in India'** explores how vaccine decision-makers at the national-level in India conceptualize CE, the evolution of CE in the vaccine arena in India, and their individual and/or institutional support to foster CE, especially during the Decade of Vaccines (2010-2020). This paper is based on the findings from the elite interviews of the vaccine decision-makers in India. For this paper, content analysis of the interviews was undertaken to identify experiences, evolution, and fostering of CE. This research followed a naturalistic ontology model and allowed to grow from the epistemology and methodology of the process (Lincoln and Guba, 1986). Though the focus was to analyze CE during the Decade of Vaccines (2010-2020), examples of social mobilization during the National Polio Surveillance Program (NPSP), in the late 90s and introduction of the Japanese Encephalitis vaccine in 2006 were critical because they had a bearing with the evolution of CE, and have thus been considered in this research.

The second findings chapter (Chapter 5 in this dissertation) **analyzes community engagement barriers and enablers for vaccination in India**. The results from the policy documents review, elite interviews with the decision-makers, and convening meetings were triangulated to identify enablers and barriers to CE for vaccinations in India were triangulated to report the findings. Results are reported using the philosophy of KFT under the SEM.

Summing up

This chapter highlights the steps involved and demonstrates the rigor in conducting a staged qualitative research study. Outlined is a detailed method of analysis using a process of thematic coding that involves a deductive coding (derived from the philosophical framework) and identifying themes emerging from participant's discussions. This careful description of the steps and processes used in data analysis can be replicated and assist other researchers in demonstrating a high degree of clarity of the conceptual framework and method of analysis applied.

CHAPTER 4

VACCINE DECISION-MAKERS' CONCEPTUALIZATION AND FOSTERING OF COMMUNITY ENGAGEMENT IN INDIA

Abstract

Introduction: India has made tremendous progress during the Decade of Vaccines (2010-2020) by introducing multiple new vaccines, along with strategic interventions like the Mission Indradhanush, and decentralized community-based vaccination delivery to ensure 90% immunization rates. Despite this progress, unmet vaccination need is very high in the country, leading to the death of around 500,000 children annually, and to the emergence of clusters of unvaccinated children in which disease outbreaks can occur. Existing evidence showcases lack of appropriate community engagement (CE) as a central tenet for vaccine resistance and backlash by communities leading to lower vaccination uptake. However, the current evidence-base neither has a consensus on CE nor is clear about its effectiveness. This study examines conceptualization, evolution, and fostering of CE in India from 2010 to the present times by vaccine decision-makers in the country.

Methods: This qualitative study was undertaken from December 2017 to February 2018. 'Studying-up' method was carried out by interviewing 25 national-level vaccine decision-makers. Study participants included policymakers, immunization program heads, and heads of vaccine technical committees from the Government, international agencies, donors, and non-profits. Data analysis was done using key CE themes.

Findings: The study identified a broad spectrum of communities and CE, rather than linear utilitarian-empowerment dichotomy. Decision-makers conceptualized 'communities' as vaccine-eligible children and their parents and vaccination influencers, like local-level healthcare providers, religious leaders, NGOs, and CBO members. CE was variously defined as community outreach, capacity-building, and information dissemination for vaccination. There was no explicit policy guideline defining CE or CE activities, especially for contested vaccines, or monitoring and evaluation related to CE. CE evolution was explicitly noted, from house-to-house polio campaigns to targeted information dissemination among vaccine resistant communities, and intensified capacity-building during the introduction of recent vaccines. Participants recommended developing an operational definition of CE in the vaccine space, codifying it in policy guideline documents, documenting CE best-practices, planning CE from the vaccine initiations stages, and developing a better understanding of communities' trust of vaccine delivery systems and policies.

Conclusions: The study recommends analyzing CE in the context and history of the social construction of vaccines among communities. Broader conceptualization of CE is needed, capturing its full range of health, social, and relational gains between communities and decision-makers.

Introduction

Decision-makers in biomedical prevention research and practice are increasingly recognizing the virtues of community engagement (CE) because it improves research efficiency, dissemination, uptake, implementation of research findings, and public perception of biomedical prevention, while decreasing the likelihood of therapeutic misconception and facilitating constitution of multi-sectoral coalitions (Fregonese, 2018; Tucker and Rennie, 2014). This has led to what some term the 'governmentalization' of CE which refers to the governmental embrace of CE, expressed by a sustained political will to integrate CE, in biomedical policies and programs, balancing technical and lay expertise, and engaging in a respectful, dynamic relationship with the community (Tindana, 2007; Carlisle, 2010; Crawshaw et al., 2003). This governmentalization of CE has invigorated the social values in government to facilitate technology transfer while empowering communities to make informed choices for biomedical prevention tools like vaccines (Milstien and Kaddar, 2006; Folayan, et al., 2015; Boxelaar et al., 2005; Kilpatrick, 2005; Carlisle, 2007; King and Cruickshank, 2010; Gaventa, 2004).

In India, governmentalization of CE in the vaccine space is mostly evident through federal investments by the government, and donated investments and contributions by trusts and foundations respectively, to strengthen routine immunization, especially in pockets of high vaccine resistance and low vaccination coverage (Griffith et al., 2011). Despite these investments and the interventions thereof, the latest national survey shows that only 62% of children (12-23 months) received all basic vaccinations (protecting against tuberculosis,

diphtheria, pertussis (whooping cough), tetanus, polio vaccine, and measles); and 63% percent received all the three doses of Hepatitis B vaccine (National Family Health Survey, 2017, Madhavi, et.al., 2005). These rates are much lower than the national targets, and progress still remains too slow for most immunization goals to be reached by the end of the Decade of Vaccines in 2020 (GVAP, 2017). This has resulted in huge vaccine unmet need leading to high vaccine-preventable morbidity and the death of around 500,000 children every year in the country (Tandon, May 2018). Public health researchers attribute this low immunization uptake to poor community participation and to community skepticism about the Government of India's (GoI) intentions for the Universal Immunization Program (UIP) (Vashishtha and Kumar, 2013).

Evidence of community skepticism and lack of vaccine support has been extensive and is seen in recurring incidents of vaccine resistance and backlash by communities such as covert to overt vaccine resistance ranging from people closing their doors and windows when they hear vaccinators approaching, to physical strife between vaccinators and communities (Larson et al., 2011). The cervical cancer-preventing human papilloma virus (HPV) vaccine's post-licensure trials, arguably the demonstration projects, resulted in negative public opinion and suspension of the vaccine introduction by the Supreme Court of India in 2010 due to adverse events and lack of CE procedures (Bagcchi, 2013). Even after the January 2018 approval of the vaccine by the NTAGI, the national government's advisory body and highest technical agency that recommends vaccines, the country's right-wing groups wrote letters urging the Prime Minister to stop any attempt to pilot the vaccine. This and prior community challenges to HPV vaccine resulted in a staggered vaccine launches only in Sikkim State, and pilots in Punjab and Delhi

States (Gangtok, Northeast Now, July 26, 2018; Prasad, The Hindu, October 4, 2017; Sputnik, June 2017; Belani, 2014; Bagla, 2013; Shetty, 2010). This is not only an issue for the HPV vaccine. In 2010, Public Interest Litigation prevented the introduction of pentavalent vaccine protecting from meningitis, pneumonia, otitis, whooping cough, tetanus, hepatitis B and diphtheria (Nair et al., 2011). Rao and Govindarajan reported decreased uptake of measles-rubella vaccination in certain states of India amidst social media rumors of political conspiracy for unsafe vaccinations (Scroll.in, Rao and Govindarajan, June 2017; Hindustan Times, Sharma, January, 2017).

In response to these incidents, there has been a growing sensitization among decision-makers in India, a group which includes policy-level people, program heads or associates, and vaccine decision-makers of the government, private sector, NGOs, and international agencies at the national-level, regarding the importance of engaging communities in the development, and eventual dissemination of vaccines and other biomedical strategies. This was particularly evident after the Supreme Court recommended meaningful dialogue with the community for vaccines and regionally- appropriate immunization strategies to help accelerate vaccination (Rao and Gopichandran, 2017; Goldstein et al., 2015; Laxminarayan and Ganguly, 2011; Madhivanan et al., 2014; Obregón et al., 2010). As yet, however, it is not precisely clear what is happening in terms of the country's efforts to engage the communities for vaccine support and uptake (Sengupta et al.; 2011).

The first step toward understanding any activity related to CE and its impact on vaccine uptake is to define and characterize CE and the efforts taken by the national government and vaccine decision-makers in 'doing' CE. Existing studies highlight ethical, political, relational, and public health imperatives of CE for vaccine acceptability in a historical context of colonialism, exploitation and marginalization (King, 2010; Hunter, 1995; Ostrander, 1995; Brukardt, 2004, Patel and Nowalk, 2010). Macqueen et al. have identified CE's varied definitions and absence of CE metrics (2015). The lack of measures is likely an outcome of difficulties conceptualizing CE or actualizing effective CE (Mcqueen, 2009; Leon et al., 2015). Thus, understanding CE in vaccination efforts should include the perspectives of vaccine decision-makers. Prior studies have not done so.

This study explores how national-level vaccine decision-makers in India conceptualize CE, the evolution of this conceptualization, and individual and institutional support for CE during the Decade of Vaccines (2010-2020) in India. Study findings will inform vaccine decision-makers of the prevailing views of CE, issues and data needs related to CE, and may trigger a policy dialogue regarding these issues. This study is timely, as the GoI is introducing several vaccines in its immunization program, which, in addition of being contested or feared by the communities, are often considerably more expensive than existing vaccines, and target diseases which are relatively 'hidden'. Therefore, broadening the understanding about these issues will respond to Greenwood's call for a concerted and strategic CE for empowered vaccine decisions, establish why CE will facilitate communities' vaccine adoption, and finally recommend CE

strategies that will enable effective uptake of all vaccines among the vaccine eligible populations (Enria et al., 2016).

Methods

Study approach

This exploratory study was conducted in India among vaccine policy decision-makers. Synthesizing the work of Angwenyi (2014), Larson et al. (2011), Gikonyo (2008), and Cvetkovich et al., (2002), the authors in this study define CE as: (1) an upstream policy imperative, rather than downstream interventions 'for the community,' (2) incumbent to sustained political-will for community-sensitive, evidence-informed, tailored vaccine policies and programs, (3) providing equitable and tangible vaccination, transparent communication, and capacity building benefits (4) enabling communities' empowered agency to critically analyze vaccine-related myths and misinformation for vaccination decisions, and (5) bringing in nuanced community aspects influencing policy recommendations while building trustworthy relationships between vaccine decision-makers and communities.

Inclusion Criterion

During December 2017 to February 2018, key informant interviews (KIIs) were conducted with a purposefully selected sample of 25 country-level immunization leaders and decision-makers in India to assess their conceptualization of and support for CE for ongoing, new, and emerging vaccines in India. Participants included heads of communicable disease control, preventive medicine, maternal and child health, and played leadership roles in vaccine

policymaking, vaccine financing and/or planning and implementing national-level vaccination programs in the field of vaccine research, development, and roll-out.

Study Participant Recruitment and Data Collection

Study participants were recruited first from the professional network of the principal investigator (Dutta) and then expanded through snowball sampling. Recruitment emails explaining the study purpose were sent in December, 2017, and thereafter followed up with phone calls to identify interest and availability in an interview. All except two participants confirmed participation in the study after two follow up contacts during December, 2017.

Profile of Study Participants

All but two participants were currently employed with active decision-making roles in vaccine programming and policymaking. One participant who retired recently is currently engaged as a Chair of various vaccine research and development ethics committees for vaccine clinical trials and pilot projects. Another participant, after retiring from the Ministry, is now working as a Consultant to a NGO active in downstream CE and policy advocacy for uptake of vaccine and other biomedical prevention tools. Both these participants thus shared their perspectives on CE while being a part of the Government earlier and now as a part of non-profits and other regulatory bodies. Most study participants had backgrounds in epidemiology, pediatrics, virology, or vaccinology, and three had specializations in humanities: medical anthropology, health management, and social work. Table 4 describes the profile and leadership function of each study participant.

[Table 4]

At the time the study was undertaken, there were no studies in India on CE in the vaccine policy formulation and program planning space. The interview instrument thus drew upon studies that had explored CE factors influencing the uptake of new vaccines and conduct of vaccine clinical trials in developing countries (Sundaram et al., 2015; Uddin, et al., 2013; Leon, et al. 2012). Semi-structured open-ended, face-to-face interviews lasting 45-90 minutes explored: (1) participant's conceptualization of community and CE, (2) evolution of CE, (3) fostering support for CE, (4) resources available for CE, (5) partnerships for CE, (6) community-level enablers of CE, and (7) community-level barriers to actualize CE. This format facilitated the free expression of opinions by participants, allowed for probing and clarification of responses, and enabled identification of new issues and topics as they arose. Interviews were conducted between December 2017 and February 2018, audio recorded, and thereafter transcribed verbatim by the lead researcher. Field-notes written within the 24 hours of each interview, reflected on the interviews from the perspective of the researcher with focus on how the study participants presented themselves including non-verbal communication.

Data Coding and Analysis

For confidentiality purposes, names and affiliations of all respondents were anonymized. Participants' responses were referred by the organizations to which they belonged to, categorized into five types: (1) MoHFW and its research institutions, referred to as the

Ministry (2) immunization technical committees under the aegis of MoHFW, referred to as technical committees, (3) UN agencies, (4) donors, and (5) NGOs.

Data coding and analysis was done using NVivo 12 (QSR International, Melbourne, Australia). Two coders joined the principal investigator (Dutta) to independently code a sample of the interviews (N=5 each). This was followed by a coding conference to negotiate consensus with 90% consistency for inter-coder reliability for final nodes through inductive and deductive methods. This helped emancipate the researcher's position in appropriate meaning making of the data (Lofland and Lofland, 1995; Stake, 1995; Maxwell, 1996). The outcome was a coding structure with 7 multi-dimensional CE themes with 42 nodes. The remaining 20 interviews were coded by the primary researcher using the negotiated final coding scheme.

Results

Study participants described their roles in leadership positions to foster and promote CE for vaccination gains. Five participants mentioned their roles in expanding CE strategies in vaccination programs in other Low and Middle Income Countries (LMICs) of Asia, Africa and Latin America, places characterized by high disease burden, low vaccine confidence, and huge unmet vaccination needs.

Conceptualization of Community

Overall, in envisioning CE as interventions *"for the community, and in the community,"* participants unanimously acknowledged that CE *"ultimately boils down to trust"* between the

decision-makers and the communities. Recollecting their own experiences, they mentioned that regular and early engagement with the communities facilitated better vaccination outcomes, even in the case of otherwise contested vaccines, like HPV, especially in the under-served areas and among minority communities.

> *"We have never faced any challenges with the introduction of HPV vaccines. We gave the first dose to the girls in 2016 and then the second doze and expanded the program in other districts in 2017. Again, whatever target we had set, we could reach almost 98% of it. We always go to the community and have media campaigns, have interpersonal communications. We use all sorts of communication channels to make people understand what we are going to introduce and give to their children."*

In defining CE, participants conceptualized 'communities' in several different ways which can be broadly categorized as: (1) vaccine-eligible and priority populations, (2) vaccine gatekeepers at the local levels, (3) local-level stakeholders who impart information to individuals, or groups in order to encourage vaccination uptake among the vaccine eligible populations, and (4) local-level stakeholders, whose messaging at a community-level influences both individual vaccination decisions and herd immunity (Table 5).

[Table 5]

Most participants conceptualized communities as priority populations for vaccines such as eligible children, young persons, and pregnant women. Ensuring full immunization to them under GoI's UIP was identified as the most important goal, and, as described later, the prime purpose for 'doing' CE. Three participants representing organizations who conducted vaccine

clinical trials explained communities as healthy, uninfected potential trial volunteers or vaccine trial participants, in addition to the communities where these people lived.

> *"Communities included adolescents and adults and in some of the areas some particular sub-populations in relation to HIV and vaccine trials like the commercial sex workers or individuals working in the health related institutions. I think we were not just limiting communities to the subset of the population who participated in clinical trials, it was the whole communities in which those individuals were living."*

Some participants identified community as vaccine gatekeepers, which included people like mother-in-laws, husbands, and religious leaders, especially in minority communities who either resisted vaccine introduction and delivery or influenced vaccination negative decisions among the priority populations.

> *"….like in Mallapuram the mother generally said 'no' to vaccination and because their husband lives in the Middle East (whom they should ask and seek permission regarding the child's vaccination). We (decision-makers) then realized that we have to find a way to tap the Indian men who are influencing immunization acceptance back home."*

While most participants suggested or narrated targeted interventions with vaccine gatekeepers, one person expressed that they avoid working with '*activists*', especially those associated with any anti-vaccine political groups.

> *"…we do not work with outright activists. We are very happy to work with the critics of us and the Government, or of the system, but not with activists."*

Most participants connoted the 3A's as "community within their own community" because they were considered trusted by the communities they serve These 3As comprised of

the Auxiliary Nurse Midwifes (ANM), or the Multipurpose Workers (MPWs), responsible for administering vaccines among < 5000 people; Accredited Social Health Activists (ASHA), and Anganwadi Workers (AWW), literally translated as 'courtyard shelter' workers, who live and are responsible for promoting maternal and child health, including interpersonal communication for full immunization coverage among <1000 priority populations.

Likewise, grassroots organizations working on maternal and child health, community based organizations (CBOs) like women's self-help groups (SHGs), religious leaders of minority communities, and representatives of unorganized occupational groups like brick-kiln workers and barbers were considered communities by all interview participants due to their role *"to help with community demand for routine immunization.*" Vaccine trial-conducting organizations considered their CABs as communities, whose role was being a conduit between the research community and trial volunteers.

There were a few instances where local-level representatives of technical and youth organizations were also referred to as communities. These included members from the local chapter of the Indian Association of Pediatricians (IAP), Indian Medical Association (IMA), Rotary Club, Lion's Club, National Cadet Corps, National Service Scheme, and Nehru Yuva Kendras, who performed advocacy and outreach work to encourage families to immunize their children against polio and promoted other vaccinations in India's highest-risk districts.

Despite expressions of heavy reliance on the 3As and local-stakeholders in meeting UIP's immunization targets, their CE roles seemed different. The ANM and AWWs were salaried staff for vaccine administration among communities, the ASHAs received honorarium for counselling and escorting the communities for vaccinations, whereas the local NGOs and CBOs informally engaged and were instrumental in carrying out community-based activities to motivate community's vaccination decisions and were conduits between researchers and vaccine clinical trial participants. Two participants, one at the Ministry and another with a GoI research institute, mentioned having Memorandum of Understanding with Rotary and Lions Clubs, and peers in local NGOs, while another with a donor organization highlighted non-financial incentives to the community-level influencers.

> *"For schools which had more than 90% coverage, we gave some felicitation*s *(certificates) to the local headman. Certificates were distributed by the Medical Officer, which motivated the community. But there was no monetary incentive."*

Some participants discussed NGOs and the media, though it was unclear whether these were considered as community or not. Again, several NGO heads, and those with an academic background in the Humanities, considering their community-inclusive approach, identified themselves as the community. In most of these expressions, it was not just the variety of conceptualizing community, but also a government versus community divide which was evident:

> *"The need for community ownership, they need to understand that they are not 'they', they are 'we'. It is all a team, not researcher and community but "us together."*

"Somehow with the Government in every country, they want to clip our wings. This is very sad because we bring up issues that are affecting the common person, which, as a Government you might not even know or see."

In contrast, the media was referred to with a caution by participants. The concern expressed was mostly *"to stop negative media"*, *"so that they (mostly meaning mass-media) do not blindly publish*.. *so that media does not overplay and sensationalize when it is not an Adverse Event Following Immunization (AEFI)."*

Conceptualization of CE

Participants' CE conceptualizations was varied and expressed as segments of processes rather than any precise definition broadly classified as: (1) vaccine policy and program formulation for vaccine introduction among communities (2) capacity-building and stakeholder communication on vaccines and vaccination (3) vaccine information dissemination among communities and (4) targeted community-level interventions each, discussed separately below. One participant stated: *"Every policy maker has a good intention for CE but there are very few recipes available for successful CE models."* Irrespective of CE conceptualization, its ultimate goal was driven to *"….understand what is going on in people's minds* (regarding vaccines and vaccinations)."

- Vaccine Policy and Program Formulation

Many participants expressed CE as a top-down approach of vaccine policy formulation and vertical delivery of program guidelines intended for vaccine-eligible populations. Participants explained that vaccine leadership begins with the MoHFW, which then delegates vaccine policy design, operational guidelines, and training modules to its technical advisory bodies such as the NTAGI, Standing Technical Sub Committee, and Mission Steering Group.

These bodies develop the program from these directives and send it back to the Ministry for vetting before dissemination to the states. A vertical, top-down structure and management was expressed as follows:

> *"If you think of a chandelier, the Ministry (MoHFW) is the hook. The different lights are the different partners, they are held at right distances in the right manner; meaning in immunization, the roles are well defined and there are very clear partnerships and no duty shedding."*

While all the participants indicated that vaccine policy was guided by the National Vaccine Policy, 2011, they could not indicate any CE specific policy or guideline. Three respondents cited the *Communication Strategy for Polio Eradication*, a document by UNICEF and USAID (CORE Group), detailing strategic communication approaches to reach the last child with polio vaccination as the nearest to a CE guideline they would envisage. Similarly, vaccine introduction and rollout, participants described, was guided by a vaccine-specific operational guideline, developed in English and Hindi (the national language of India) at the national-level, which were thereafter disseminated to the states. Participants mentioned that specific revisions suiting socio-cultural needs or translation in the local language were mostly done at the state-level, though there were no examples of any material where any special item was added, removed, or edited to address the community-specific needs.

> *"…the guidelines goes from the Ministry to the state and then they modify it if they think that something is to be added or deleted."*

Decisions to introduce new vaccines were made at the Ministry level after the vaccines were licensed. The MoHFW and its technical advisory groups would consider factors such as

disease burden, vaccine cost, cold-chain, and supply chain issues. Most participants at the Ministry, donor organizations, and UN organizations acknowledged financial support of the MoHFW and the international donors, and were optimistic about the recent strategic endeavor by the MoHFW through its Mission Indradhanush (MI) and Intensified Mission Indradhanush (IMI), targeting 90% coverage by the end of 2018.

> *"… Immunization is a vertical program and the central ministry bears all the operational and logistics costs. States are supposed to implement that."*

More than half of the participants, while noting vaccination policy and guideline dissemination as CE, criticized chasms in this one-way, top-down policy formulation and program delivery. They did identify limited spaces like the Village Nutrition and Sanitation Days (VHND) - organized once every month at the AWC the rural child care center - for priority populations and local stakeholders to express their viewpoints, if any. However, heads of five organizations and technical bodies expressed that this, *"working in silos"* was *"not real CE"*

> *"The system creates silos which can be a disadvantage. Every policy maker has a good intention for community engagement but there are very few recipes available of successful models of community engagement."*

- Capacity building and stakeholder communication for CE

Another predominant conceptualization of CE was building the capacity of the vaccine implementers (the 3As) so that they engaged effectively with the community in motivating them to be fully immunized. This occurred through capacity-building trainings conducted by the GoI and UNICEF on the usage of IPC and SBCC materials and vaccine-specific operational

guidelines. Participants at the Ministry and UN organizations discussed the Training of Trainers (ToT) imparted by the national and state-level immunization officers using the Boosting Routine Immunization Demand Generation (BRIDGE course). Though considered comprehensive, most decision-makers thought that three days stipulated for the BRIDGE course was rather insufficient to train the frontline healthcare providers on all aspects of CE. Linked to this, the participants strongly felt that the 3As were the ones to 'do' CE, because direct CE from the GoI level is not feasible. Only one participant stated contrary to this, indicating that leadership's presence was desired at the community-level.

> *"Communities want the leadership to come to them and talk to them. …just sit with them, work with them and that is the key to CE. The leader does not need to go to the community every time. But at least once or twice if he or she goes, it really increases the confidence of the community."*

In addition, there were several examples of training the local-level influencers, such as: CABs, peers, local religious leaders, and members of CBOs, to build community-level champions, who in turn, played multiple roles to: facilitate the vaccine providing organization's entry to the communities, work as effective conduit between the researchers and communities, and eventually help vaccination uptake or effective conduct of vaccine clinical trials:

> *"As a XXX researcher, if I went to the community nobody will accept me, but they will listen to the peers. So peers became the voices of our organization. They were also telling us about community needs. Each NGO would have 20 peers and we trained them."*

Again, participants were divided in their perspectives about whether the cascade training of the 3As or TOTs of the local stakeholders was an expression of CE, but it did appear as if CE was delegated to them:

> *"So, you piggy back everything that the Community Health Worker, who goes and talks about immunization, family planning, maternal health, school health, adolescent health, non-communicable diseases, and cancer…* [but] *you are not actually engaging or doing CE."*

One participant mentioning the structural gaps, critiqued the flaw in defining CE in this way:

> *"The Immunization technical Unit was not built with a community engagement model for immunization. Like you compensate ASHAs for children fully immunized and trainings attended not for CE."*

- Dissemination of Vaccine Information

Most respondents, despite realizing that information sharing and dissemination of interpersonal and socio-behavior change communication (IPC and SBCC) is an oversimplified and incomplete definition of CE, admittedly used 'communication' and 'CE' interchangeably, and mentioned that "*CE is messages sent down*" (for vaccination uptake). One participant repeatedly mentioned, *"The role of CE, I mean communication, sorry using the wrong word again."* In the same vein, the Communications Officer was denoted as the human resource for CE by almost all the participants. Community-based social mobilization and communication, participants said, came in waves, and was most noticeable during vaccine introductions, before and during vaccine trials, in case of a disease outbreaks.

One participant conceptualized this form of CE as bilateral information transfer, another understood it as a means for communication between the community and government. Some remained top-down, describing CE communication as question/answer sessions to increase vaccine uptake:

> *"….we sat with communities and asked if they wanted to talk with us. So, we would ask, why the children were not getting immunized. Then they would ask what the harm is if they did not get immunized? Or what is the advantage of getting immunized? So you would sit down and answer their questions."*

This same conceptualization also held the information to be going the other way: from the community to the government in service to the vaccine program goals:

> *"…so, the feedback came from the panchayat leaders, ASHAs, and the community. …like if you have identified a construction site, did the mapping and when you entered the data and reached the community after a fortnight, they have already moved. So the local person could tell us the whereabouts of the mobile community and we could reach them through the ASHA network."*

Another participant from a state which had piloted the HPV vaccine, highlighted the critical importance of vaccine information dissemination in doing CE and meeting vaccination targets:

> *"…we could reach almost 98% target. We always have media campaigns, go to the people and have interpersonal communications. We use all sorts of communication channels to make people understand what we are going to introduce and give to their children to protect them from certain diseases."*

Another component which the participants mentioned was information dissemination through media trainings, *"State Immunization Officers are trained on how to handle the media."* Similarly, sensitization of the media was mentioned mostly as a means to *"stop negative media" especially regarding Adverse Events Following Immunizations (AEFI), so that the media does not over-sensationalize when it is not an AEFI."* This is linked to the earlier expression where media

representatives were treated as a part of the community by some participants, while others did not agree to this nomenclature.

Increasing trends of engaging with celebrities and local officials as role-models to motivate communities' vaccination decisions came across as another communication channel for CE by some participants, while quite a few expressed otherwise, and were unsure about the effectiveness of this strategy to involve communities or ensure vaccination uptake.

> *"So, we used to keep the vials in front of the community and ask them to choose, whichever they wanted. We said we do not differentiate between a Hindu and a Muslim child. The Deputy Collector used to vaccinate his child in the* (community)*, and then they* (the vaccine eligible adults or those with vaccine eligible children) *believed."*

> *"I think our communication campaigns are pretty pathetic. I mean what is the point in having a XYZ (an iconic film star and a celebrity in his 70s, now) there? I mean that he is there on every advertisement. We have no way of measuring that. Does he convey safety of the product? To sell a toothpaste or a phone we spend hundreds of millions of dollars, just to really understand the consumers mind and to figure out what triggers things. How much is going into selling something far more important as vaccines?"*

Three participants, considering the diversity in India, said, "*Every mile the language changes, the culture changes*" and favored having a "*village-level communication strategy."* Describing vaccine information dissemination using traditional mechanisms like print and mobile mediums, some participants highlighted the need to explore use of web-based social-media platforms like Facebook, WhatsApp and Twitter, considering digital media's easier usage, cost effectiveness, and penetration in interior areas of the country:

> *"Earlier messages were through mobile texts. Who is there to read your texts? Nobody is interested. So, messaging is getting more and more creative. So, if my GIF is giving a message there is more likelihood that people will pass it on."*
> *"…in the rural areas, maybe 50-60% would use Facebook. Versus 100% use of text messaging and WhatsApp."*

- Targeted Intervention and Community Emancipation

Participants generally held a utilitarian conceptualization of CE as a mechanism to *"increase vaccine demand generation*."

> *"…(W)e are currently planning to work on demand issue which will involve the community through social mobilization."*

While there were several expressions of CE as targeted program interventions, responses showcased a wide range, from top-down enforcement of vaccination on communities to respectful engagement with the communities, typically with vaccine gatekeepers and minority populations, especially in areas of high vaccine resistance and low vaccine confidence:

> *"In XXXX district (name not disclosed) community was very resistant and they were not even allowing the vaccination team. Yes, physically resisting, they started beating us. Then we had to contact a local muscleman, briefed him, convinced him that this* (carrying on with the vaccination drive) *is important, and then told him to make an announcement that vaccination is not a bad thing."*

> *"We engaged universities like Aligarh Muslim University, Jamia Milia Islamia and Jamia Hamdard, and their staff went out to the field to orient the local religious leaders so that they spoke with the communities. That also helped to address the issue of hesitancy."*

Some participants highlighted best practices from the earlier NPSP period like the '*Underserved Strategy,'* which had its genesis after a polio outbreak in Uttar Pradesh in 2002 among the Muslim populations and the *'Social Mobilization Network'* formed in 2001 as a direct intervention to reach out to families to immunize their children against polio. As another example of CE, a participant mentioned '*My Village my Home' (MVMH).* It is a pictographic vaccination tracking method in the shape of a hut, with vaccination details of each new born

child born in the village that year, filling each brick in each column of the hut. The project was under the Maternal and Child Health Integrated Program (MCHIP) funded by the USAID Bureau for Global Health under its flagship maternal, neonatal and child health (MNCH) program (Sample picture of MVMH in Appendix C). This would be posted in the health sub-center (SC), and allowed each parent to identify if they had missed any vaccines for their children. Participants perceived these peer-conversations and vaccine sensitization as CE leading to the community's empowered vaccine decision making.

In designing community-sensitive vaccination programs, and ensuring that efficacious vaccines become effective among communities, one respondent said, "*it is a marathon, and not a sprint."* indicating CE as a time-and resource-intensive process. Another reiterated, *"See, CE is an expensive process. It took me 20 years to learn about community and how to engage with community."*

While several participants envisaged ideal CE as a community empowering process, one participant cited the example of HIV and conceptualized CE as a way to develop community's agency.

> *"HIV has set an example for other diseases also of how communities can get engaged, how they can advocate for their own cause and then there could be an equal partnership between a practitioner, community and the programmers. So, HIV is a success story in our country. We are seeing HIV control through community engagement."*

One participant conceptualized community agency and stated CE as:

> "*Demand generation is another thing. It means that you* (government/vaccine providers) *are giving we* (vaccine eligible community) *are accepting, and policy*

influencing is that where the community thinks that certain things needs to be changed or certain things which they have issues in accepting the way it is being delivered or designed. Like, if the community thinks that oral vaccines are easier than the others, are they influencing the government to change?"

Fostering of CE

All the participants acknowledged the value of CE for vaccination uptake and reducing vaccine hesitancies, though the description of how they championed and advanced CE during their decision-making roles covered a spectrum. In some cases, relationships among decision making organizations appeared to be fractious. Most of the participants recognized issues of incompatibility between scientists and communities, admitted that practicing the right CE is a complex decision, aspired to re-examine the starting point for CE, and recommended the need to expand the accountability of decision-makers to communities. They also felt that an overall sense of trust of communities for vaccines needs to be instilled, so that each time a new vaccine is introduced, incidents of community resistance and backlashes do not re-occur. For example, one participant said:

"… but the moment you come back, it will be the same thing again. The moment you leave the village, others will come and say, 'Are you mad that you listened to these people and got your child vaccinated?"

Responses from participants' narration of their roles in owning, advancing, and integrating CE with immunization efforts could be categorized in a spectrum of seven different expressions. Though a strict categorization of responses by organizations would not be accurate, patterns of CE-fostering roles by participants' organizations could be deciphered.

(1) The first was a single example from a research institution where the priority community's emancipatory role was acknowledged by its Director.

(2) The second kind of response showcased reliance on frontline healthcare workers for CE and vaccination delivery, mostly expressed by the technical and program heads.

(3) The third were those responses where organizational structure and policies supported inclusion, and the senior management team was both knowledgeable about community-level issues and had intermittent direct connect with the communities. These responses were mostly from the vaccine research organizations.

(4) In the fourth group, there were participants who often went out of their way and proactively did CE activities and innovative interventions because they thought that it would help the vaccination outcomes of a certain community. This group mostly had participants who were responsible for the introduction and roll out of vaccines, especially in under-served areas or where its uptake was low.

(5) In the fifth category, there were leaders who thought CE should be done because it was mandated by the national government or by global leadership. These were mostly from the Ministry, GOI level.

(6) The sixth kind gave examples where they propagated CE because it was central to performing one's duty.

(7) The last were those responses where vaccines were imposed on the communities using force, with responses from program heads, who had to meet certain vaccination targets.

All the seven categories with one exemplar quote for each category are summarized in Table 6.

[Table 6]

In expressing how they owned or fostered CE, each participant cited several examples of community-specific outreach and targeted interventions during their tenure. These incidents took place during vaccination campaigns, vaccine introductions, or as a part of routine introduction, wherein vaccination uptake among eligible populations had to be ensured. Therefore, these interventions often signaled innovative strategies to ensure vaccination in the program under reached areas, and among the minority communities where suspicious regarding vaccination as another political agenda to selectively use anti-fertility agents were the highest. Again, most of these examples reiterated a critical reliance on local stakeholders and health care providers as catalysts in converting vaccine hesitant behaviors to vaccine adoption behaviors. However, participants did not mention any institutionalization to sustain, replicate, or scale-up any of these unique strategies. Some examples were as follows:

> *"Among the migratory brick kiln workers many children remained unimmunized. So we approached the brick kiln owners and got the list of all the children which we sent to the Government officials so that these children were vaccinated. Because there were 1000s of brick kilns and if you left them out then you do not vaccinate 1000s of children!"*
> *"It was also very difficult to catch hold of fathers, who used to go to work in the day. So we thought of another strategy, because the men will talk and not listen. So, we went to the barbers' shops. That was the only place where the men used to shut up or else they would get cut. XXX* (The Information, Education, and Communication Officer) *gave some danglers to the barbers and then they were trained. We also approached the barbers' associations."*

Evolution and transformation of CE

While all the participants admitted that CE in the vaccine space has evolved since 2010, they mentioned that the communities' memory of top-down impositions of prevention methods/tools by the system had impacted communities' lack of vaccine confidence over these years. One person said:

> *"..the vaccine fear was connected to the family planning program, when women were forcibly sterilized."*

As an aftermath of this top-down imposition sterilization programs, erroneously poised as CE, participants noted that CE's relational gains have been affected and that the trust between the community and systems have been damaged over the decades. Relevant quotes are as follows:

> *"The trust in the system, the trust in the research, in the manufacturing, regulatory, also the policymakers trust who administer the vaccines. And so a clear understanding of each other's trust is important, because ultimately the immunization relies on trust."*

> *"….it is very difficult to build trust in the community...like we told the XXXX worker, 'don't put the picture of a pregnant lady on the IEC material, because immediately the community will relate it is with pregnancy and have the notion that something will happen to the newborn child.."*

In summary, all participants indicated that understanding about CE was still evolving, and that it was a *"very poorly understood space," "complex,"* and *"several gaps to understand this puzzle."* Three participants critiqued that in practice CE is *"offhand," "ad-hoc practices to douse the fire," "firefight,"* or "*control big chaos and help put things back to normal"* and called for *"real community engagement"*, and a *"scientific approach to CE."* One participant from a research institute mentioned:

"We were not really very serious and formed a small community group. (Initially, the community group) *heard us, had some snacks and went off. CE really didn't go beyond that. But by then at high level institutes* (NIH and USAID funded projects) *CABs had become really very active and CE became an important area* (of development and intervention) *for us."*

Most participants acknowledged the push and handholding to understand and implement CE from global donor partner organizations, and some described direct involvement of the GOI in recent times, in acknowledging the importance of CE for ethical conduct of vaccine trials and effective uptake of vaccines. Specifically, the financial support and capacity building by the GOI, the U.S. Centers for Disease Control and Prevention (CDC), the WHO, GAVI - The Vaccine Alliance, and the U.S. National Institutes of Health (NIH), were mentioned. This evolution can be seen in the following exemplar quotes:

"IAVI has done in-person hand holding because they had a country office whereas NIH always looks for community engagement. So unless you have community engagement, I do not think that you will be considered also. Initially we had a CAB because NIH wanted it. But then we learnt how necessary it was."

"GAVI funding, which partly went to cold chain strengthening but partly also went to improving community mobilization."

In narrating the evolutionary process of, participants in the Ministry provided a few examples showcasing genesis of a two-way, direct interface between communities and policy-makers.

"..there is more CE now after the new Government has come. The Prime Minister's Office invites suggestion from the public. Many things come to us through emails and we reply to them also."

"In the MI program our Health Minister goes directly to the ASHAs and ANMs of each village..we issue letters to each and every ASHAs and ANMs."

While being optimistic about the CE in the current times, several participants indicated a need for more regular, direct, and lateral rather than top-down discussions between decision-makers and communities, and emphasized documenting the qualitative and relational gains of CE:

"If we close the doors once again to the community, we might not get the communities back, ever again. We will lose trust and lose what we had promised."

"I think, as a country, I will not be ashamed to share, very poor in documenting. The learning that have come out of polio is so humungous ... but you will hardly see any papers. This is so because the people who are doing it do not have the time and the capacity to do that."

Discussion

To the best of our knowledge, this is the first study outlining conceptualization and support for CE by national-level vaccine decision-makers in India. To date, there had been no 'elite' interviewing in this field of study in India, possibly considering methodological, and reflexivity issues, and that vaccine introduction processes and community resistance were playing out in real time (Lancaster, 2017). Thus, an inherent challenge to this study was that it would have been difficult to find alternative interviewees if any study participants declined to take part in it. Another methodological challenge was gaining access to the study participants in the Ministry, and more so to building trust with them during a limited time, especially, those with whom the researcher was interacting with for the first time. However, the researcher's familiarity with some of the study participants who were not in the Ministry, understanding of

the vaccine governance and gatekeepers at the national-levels, knowledge of opening question which would be of interest to the study participants, and an overall sensitivity about the strategic vaccination environment in the country helped to circumvent these anticipated relational and interaction barriers (Kezar, 2003).

In carrying out this study among 25 purposefully selected vaccine decision-makers, being an Indian, knowing the field, and being from an American university gave me (the primary researcher, Dutta) an elevated status of an 'informed outsider' and allowed for considerable interpretive latitude and probing opportunities within discussions, and put the researcher in the context of an insider (Laurila, 1997; Hunter, 1995; Bowen, 2005). Some of the study respondents were initially reluctant to interact candidly. This was partly because of bureaucracy, but mostly because policymakers were busy in planning the introduction of multiple vaccines, and addressing media outrage and concerns regarding vaccine safety and efficacy, or were occupied with executive meetings preparing answers for vaccine-specific questions raised in the then ongoing Winter Session of the Parliament, which the Health/concerned Minister is obliged to answer. Notably, all of the community uproar in the NCR and several other states demanding stalling of the HPV and M-R vaccines has taken place during the same time (Cheatham, February 26, 2018 Duke Global Reproductive Health Indian Express, Saxena Dec 2017; Firstpost, Nair, Dec 2017). Due to these tumultuous circumstances, researcher's readiness and flexibility to re-schedule appointments after office hours or on national holidays, spending additional time and money for follow up calls and visits to the participants' offices, were important to carry out these interviews effectively. Literature on in-

depth interviews with elites and government officials have highlighted flexibility and knowledgeability on the researcher's end as key (Conti & O'Neal, 2007; Stephens, 2007; Berry, 2002; Harvey, 2011; Thuesen, 2011; Zuckerman, 1972). Future researchers involving 'studying elites or studying up' should be conscious and sensitive about the topic and the country's political environment to ensure objectivity and integrity of the data (Sabot, 1999; Welch et al., 2002; Shenton & Hayter, 2004, pp. 223-231).

The choice of India for this study was both appropriate and pertinent because the country's Vaccine Policy (2011) recommends generating community acceptance for new vaccines as also maintaining confidence on the existing vaccines, especially where community's vaccine resistance is reported. Moreover, in the current context, the country has been declared polio-free after years of an intensive polio vaccine campaign has introduced four new vaccines in its UIP during 2017, and through the GOI's IMI, aims to accelerate vaccination coverage to at least 90% of children by 2020 (MoHFW, Govt. of India). While we had located several studies examining vaccine research and roll-out analyzing CE, most of them were project-or-program-specific, describing community vaccine utilization, vaccine clinical trial participation, or examining vaccine confidence and trust. None was a country-specific study examining decision-makers' overall meaning making of CE, or summarizing what has been done till date to improve CE (Gopichandran, 2017; Ozawa and Stack, 2013, Mcqueen et al., 2015; Newman et al., 2011; Larson et al., 2016).

Interviews with organizational heads and immunization leads clearly elucidated that decision-makers, by virtue of their long experience in India and other LMICs, were knowledgeable and sensitive about the local, historical, and social contexts of marginalization and exploitation affecting the community's relationship with public health systems and authorities. This study did not identify a consistent or a neatly-fitting definition of community, and found CE that is an evolving process rather than an endpoint. These narratives explained study participants' own interactions with communities during their tenure, and highlighted how the CE interventions were reframed by social, bioethical, disease, and donor demands. However, these examples were context and individual-specific and thus cannot be generalized to other settings.

Despite an egalitarian understanding of CE, most participants failed to make the leap from the top-down community mobilization, targeted at achieving immunization goals, to approaches working in consultation and partnership with communities. O'Mara's systematic review of CE and health inequities also found a higher prevalence of utilitarian approaches than empowerment approaches (2013). Arnestein's Ladder of Citizen Participation defines these as community-entry interventions and classifies them as 'manipulation', 'therapy', 'informing', 'consultation', and 'placation' rather than empowered elements of CE showcasing 'partnership', 'delegated power', or 'citizen control' (1969). Also, it was observed contextual nuances wherein participants displayed aversion of working with activists and anti-vaccine lobbyists, which is an exclusionary way to conceptualize communities. Such a perspective is not consistent with the 'whole community approach', which is considered the most inclusive and dynamic

conceptualization of community (Morton and Lurie, 2013), and might risk having any CE strategies tailored for these sub-populations (Howard-Grabman, 2017; WHO, 2017). However this is very understandable, in the context to ensure vaccine introductions and uptake while needing to deal with hostile media, and community-level uproars.

Leadership's utilitarian orientation toward CE was also evident in their usage of incapacity-laden (rather than asset-based-words) like ruralites, urban slums-dwellers, vaccine-hesitant, poor, illiterate, those from minority religions, and those residing in the vaccine under-reached areas while defining the communities. While this utilitarian approach might be the most feasible to accomplish the vaccination mission in India, it defies the core of participatory work and could possibly inhibit progress toward having communities with vaccine-empowered decision-making capacities. Similarly, most participants' silence regarding the internal chasms between the 3As due to their different professional roles, accountability mechanisms, remunerations, and power inequalities with the communities (Amin, 2005; Eversole, 2010; Mosse, 2005) risks reifying communities as internally homogenous entities. This is not accurate, especially given the class and caste-based diversities prevalent in India.

We argue that a paradigm shift is needed from a reductionist approach of viewing communities (but not all the communities), especially those who avail vaccination services as the non-vaccinated, vaccine-hesitant, to seeing them as integral parts of the policy and delivery systems and recognizing their potential to play an active role in addressing vaccination uptake. Literature indicates that such a 'beneficiary-oriented' conceptualization of community and CE

can limit formation of trusted, sustainable collaborations with the communities, ultimately compromising generating critical qualitative information about communities, which only participatory research could render (Morgan, 2001; Taylor et al., 2005; Kilpatrick, 2009; Larson et al., 2015; Dutta et al., 2018; Tindana, 2007, Shonkoff, 2011).

The top-down structure of vaccine policy making and programs, which often function as technical collaborations rather than soliciting communities' active input on program or policy building, mirrors the 'two-communities thesis', which postulates that scientists and decision-makers not only find it difficult to interact with non-scientific stakeholders, but even consider 'doing' CE [from the national-level] as an ignoble business, thus reducing the potential to build community support, advocacy, and trust (Choi et al., 2018, Lin and Gibson, 2003 and Carlisle, 2010). While Ramsbottom and colleagues (2018) suggest that national government-mooted public health initiatives might not be able to stray too far from a centralized approach, critical scholarship by Adhikari et al. has defined such top-down unidirectional CE as 'short-hand' (2016), often resulting in wasted resources, with the potential to create mistrust rather than enhance benefits, create legitimacy, or share responsibility (Ukpong 2008; Newman, 2006; Dickert & Sugarman, 2005).

Incumbent to meeting the ambitious vaccination targets under the MI and IMI, CE often came across as an impromptu reaction rather than being embedded as an integral approach, mostly to fulfil donor mandates or deal with communities' vaccine-related fears. Interestingly,

Carnegie et al. (2017) work states these approaches as barriers to CE planning, essentially to fulfil donor mandates.

The deeper ambiguities regarding 'real' and 'right' CE, particularly in the face of recurring evidence of the communities' shattered trust on vaccines and vaccine-provisioning systems, was concerning. Such a conceptualization render CE as a mere check-box or service-add-on intervention, or just a signal of commitment such that, in the longer run, communities might become agents of the government, especially, when interventions are largely funded and offered at the discretion of the government and other donors (Dutta et al., 2018; Magtymova, 2007; Head and Ryan 2003; Head 2007; Paterson & Larson, 2012; USAID, 2017). Here, CE could merely be a self and donor-ask fulfilling strategy, as Cooke and Kothari (2002) have argued, and though stakeholders were seemingly 'engaged', the modes of engagement are significantly nuanced and influenced by the existing donor-partner-government power dynamics. Similarly scholars have recommended examining the relationship between interventions and communities leading to changes in resources, capacities and cultures, rather than isolated impact evaluations of interventions (Hawe et al. 2009).

Existing literature, has suggested signing memorandums with local partner organizations and beginning CE at the study design stages, which has not been the case with most programs in India (Lavery et al., 2010; Folayan et al., 2015). Further, studies show that although social media messaging is a cost effective mechanism for vaccine information dissemination by decision-makers, it might not be an effective mode of communication for everyone, and could

leave out populations who might be the most vulnerable to vaccine-preventable morbidities and mortality, many of those who are illiterate, lacking social media literacy, or are in locations with little or no internet, or are in situations where the language might not be tailored to the local dialects (Nepal et.al. 2012).

Increasing interest in CE may require emphasizing its capacity to build transparent, meaningful, collaborative, and trustworthy relationships between community groups and decision-makers by strengthening each community's agency for its own health, while addressing health inequalities, social exclusion, and the underlying social determinants of health (Carlisle 2001; Crawshaw et al., 2003, Department for Education and Skills, 2004; Leon et al., 2012). While in the current context several programs like the Grand Challenges Ethical, Social and Cultural Program, the NIH's community-engaged research through its Clinical and Translational Science Award, and the SAGE working group exemplify increased foundation and federal funding and political commitment to support CE via research, networks, and communication interventions, concerted brainstorming for a more inclusive definition of CE and CE metrics for biomedical prevention tools like vaccines is highly recommended (Fagnan et al., 2010; Lovan et al., 2017; Cavaye, 2004; Chalmers, 2004; Zerhouni, 2003). Specific mention of CE and CE outcomes in vaccine policy documents, with multidirectional and multiple points of exchange to understand and implement CE, is likely critical in realizing India's immunization goals, while also building communities with empowered prevention choices. More narrative inquiries to further understand when and how engagement should start, best practices in

building a communication loop, and a deeper analysis of the relational outcomes of CE are recommended.

Conclusion

This paper has brought together the narratives of CE in the vaccine policy and praxis space by vaccine decision-makers in India. While there is growing impetus for CE by vaccine decision-makers, studies on the longer-term relational gains of CE, and its incorporation in policies will help more effective understanding and implementation of CE. Power imbalance created by the heavy reliance on Northern donors, and decision-makers' traditional outlook about communities as 'beneficiaries', rather than 'participants' needs to be revisited. Future studies need to identify social and relational indicators of including social structures, which can track changes in vaccine sentiments among communities. Promoting CE without interrogating the terms of such arrangements can be counter-productive, creating new structures that might unintentionally reinforce potentially harmful social structures and mistrust between communities and decision-makers.

CHAPTER 5

USING THE SOCIAL ECOLOGICAL MODEL TO ANALYZE COMMUNITY ENGAGEMENT FOR VACCINATION IN INDIA

Abstract

Introduction: There is high-level policy consensus that community engagement (CE) improves vaccination uptake and reduces burden of vaccine preventable diseases. However, to date, vaccination barrier studies in India have not focused on CE, nor identified enablers and barriers for CE affecting vaccination uptake in India.

Materials and Methods: Key informant interviews were conducted in India among 25 national-level vaccine decision-makers and triangulated with 24 national-level vaccine policy documents and researcher field notes from December 2017 to February 2018. A follow-up meeting was conducted with participants in December 2018 and January 2019 to verify observations. The Social Ecological Model (SEM) is used to organize and report study findings.

Results: There were more CE barriers than enablers identified at all SEM levels. Policy-level enablers included political-will and policy documents promoting social mobilization, whereas barriers were lack of a CE strategy document and an ambiguous understanding of CE. At the organizational-level dissemination of Social-behavioral Change Communication (SBCC) materials from the national-level to the states was considered a CE facilitator, while power-relations in the community, lack of family-centric CE strategies, and paternalistic attitude of decision-makers with communities and NGOs were considered CE barriers. At the Organizational-level,

partnerships with local organizations were considered CE enablers, while lack of institutionalized support to formalize and incentivize these partnerships were barriers.

At the interpersonal-level, SBCC training for healthcare workers, sensitive messaging to communities with low vaccine confidence, and social media messaging were considered CE facilitators. The lack of plans to manage vaccine related rumors or replicate successful CE interventions during the polio campaigns for newer vaccines were seen as CE barriers.

Conclusion: Future studies should attempt to associate these identified factors with particular CE outcomes such as participation or community support from vaccine policy making stages to its uptake, or sub-population based incidents of community resistance hindering vaccination uptake. Developing operational definition of CE, having step by step policy guideline for CE, communication materials considering intersectionalities within communities, and CE indicators in national datasets is recommended. Additional studies should document CE best-practices and study implementation and effectiveness CE interventions in the vaccine space.

Keywords: Community engagement, barriers and facilitators, Social Ecological Model, Vaccine, India

Introduction

Countries increasingly are encouraging community engagement (CE) in planning and implementation of activities to improve vaccination uptake and completion (Oyo-Ita et al., 2016). This is likely because CE has been effective in mobilizing communities for uptake of vaccination services, which reduces the burden of infectious diseases, increases herd immunity thresholds (Betsch et al., 2017), promotes health equity, and enables countries to achieve the Sustainable Development Goals (Tadesse et al., 2017; Pramanik, et al., 2018).

India is one of the 194 member countries who endorsed the World Health Assembly's Global Vaccine Action Plan framework envisioning that communities understand the value of vaccines and demand immunization as their right and collective responsibility, with a goal of reaching 90% immunization coverage at the national-level (Cherian and Okwo-Bele, 2014). However, the latest available data from by MoHFW show that India's vaccination rate is 62% (NFHS 4, 2015-16). To increase the coverage, in 2014, the Government of India's Ministry of Health and Family Welfare (MoHFW) launched Mission Indradhanush (MI), and in 2017 launched the Intensified Mission Indradhanush (IMI), especially targeting communities who are mobile or isolated, and populations with low vaccine demand and/or high vaccine resistance (Gurnani et al., 2018). There are also persistent caste, class, and gender-based inequalities in vaccination outcomes in the country (Pramanik, et al., 2018; Pande and Yazbeck 2003).

Most studies focusing on communities' non-vaccination identify vaccination refusals and hesitancy as issues, attributing them to religious, social, and philosophical reasons (Pelčić et al.,

2016, Shankar and Dutta, 2010), lack of trust of the vaccine providers (Muñoz et al., 2015), fear of vaccines, and adverse outcomes following immunizations (Goldstein et al., 2015). Weigmann (2017) identified mandatory vaccination as an infringement on freedom of choice in the community. Another study partly attributed lower vaccination rates to the top-down structure of India's immunization program; the national-level defines overall policy and financial decisions, states determine implementation, including allocation of resources, and local areas conduct interventions (Pande, 2003). These findings are reflected in perceptions that interventions framed as CE are 'scare tactics' (Larson et al., 2011), or top down information provision campaigns without opportunity for community involvement in planning, monitoring, and surveillance activities (Donaldson & Preston, 1995; Sabarwal et al., 2015). Such interventions are often cited as examples of community mobilization (WHO, Ebola Training Community Engagement) rather than CE. Salathé and Bonhoeffer (2008) suggest that this lack of CE causes lack of trust in, and delegitimizes vaccination programing (O'Neill, 2002; Yaqub et al., 2014). Other scholars attribute vaccine hesitancies, refusals, and even backlash to questionable or nonexistent CE efforts (Mellerson et al., 2018; Jansen et al., 2003).

Vaccine decision-makers or 'elites' (Aberbach and Rickman, 2002) by virtue of their knowledge and position of authority as well as vaccine policy documents, drive policies and programs from the national-level, and can jointly elucidate the complexity and effectiveness of CE implementation in order to improve vaccination coverage (Rhodes et al., 2016; Pope, Mays, & Popay, 2006). However, literature on intensive elite interviews, also referred to as 'studying-up models' (Hoch child, 2009), highlight that they are infrequently conducted because these

people are hard to reach, surrounded by gatekeepers, and have the power and ability to protect themselves from intrusion and criticism (Hunter, 1993; Laurel, 1997). Thus, this study followed elite interviewing using personal resources and unique methodologies, with the aim to identify enablers and barriers to CE for vaccination services in India. Synthesizing information on elite CE conceptualization and implementation would bridge this evidentiary gap and enhance current literature which is mostly based on views of communities, or local stakeholders (Habib et al., 2017; Johri et al., 2015).

Materials and Methods

Data Sources and Inclusion Criteria

The study employed a multi-method qualitative approaches to identify the key enablers and barriers to CE for vaccination uptake in India. The data sources consisted of (1) a set of semi-structured intensive elite interviews with vaccine decision-makers in India, supplemented by follow-up convening meetings with these participants to clarify particular points discussed during the interviews; and (2) national-level vaccine policy documents in India.

For this study, 'elites' were defined as vaccine decision-makers who had been in positions of authority [of at least 7-10 years] and were responsible for: formulating vaccine policies and programs in India, signing off on the introduction and roll out of vaccines under the UIP, and carrying out vaccine clinical trials between 2010 and the present. 'Vaccine policy documents' refers to any national-level strategy, and/or guidelines in India with the purpose of sensitizing frontline stakeholders on the immunization goals, and the communities on vaccination gains;

jointly published since 2010 by the MoHFW and the National Health Mission (NHM)- India's flagship health-sector program to revitalize rural and urban health (Harvey, 2011; Mikes, 2012).

First, an exhaustive list of 30 vaccine decision-makers was prepared based on informal discussions and networking by the primary researcher (Dutta). This list was taken to represent the national-level vaccine decision-makers and immunization partners in India; 28 elites were selected from. Of the total 30, two could not be reached out to because one did not have a physical office in India, and another could not be contacted. Initial recruitment emails were sent to 28 individuals in December 2017 explaining the study purpose and seeking their consent to participate in a one-on-one in-person interview. Follow-up emails and phone-calls were completed in early January 2018.

Second, Boolean internet search was conducted to identify pertinent vaccine policy documents from October to December 2017 using the following search string: 'vaccine' AND 'policy' OR 'guideline' AND 'India.' The result was 20 policy documents. Additional documents were identified by study participants. All documents were available on the websites of the MoHFW, NTAGI, country offices of the WHO, UNICEF, and CGPP. Inclusion and data collection process is explained in Figure 3 in the Methods section in the earlier chapter.

This paper uses SEM as an organizing framework for data analysis because it describes factors at multiple levels, including intrapersonal, interpersonal, institutional, community, and policy. The selection of the SEM reflects the multi-level nature of vaccine interventions, and

likely attempts at or conceptualization of CE. For example, policy-level factors include policies and regulations affecting communities and institutions, community-level factors are often functions of the relationship among different institutions within communities, organizational-level factors constitute institutional organization and management, interpersonal-level factors include interactions of individuals with families, peers, neighbors, and healthcare workers, and individual-level factors include vaccine-related beliefs, values, and other individual factors (Crosby, Salazar, & Decremented, 2013; Oku et al., 2017; Rainey, 2011). Although SEM is a widely accepted model, and used in several vaccine studies (Kumar, 2012; Nambe, Hal, and Kamden, 2016), and vaccination and vaccine clinical trials have studied communities', program personnel's and healthcare providers' perceptions of enablers and inhibitors of CE (Kirk dale, 2016; Wising, 2012), no study has used SEM to characterize and understand barriers and enablers to CE for vaccination in India.

Data Collection

Interviews were conducted from December 2017 to February 2018 in the country offices of the participants, in the National Capital Region, which is in or around New Delhi, the capital city of India. Interviews were audio-taped and field notes were taken in parallel. Since the outcome variables of interest were barriers and enablers to CE, the questions in the interview guide addressed the following broad areas: participant conceptualization of CE, the evolution of CE specifically during vaccine introductions, and positive and negative factors which affected fostering CE during their tenure. In the earlier chapter, I have defined the conceptualization of

CE (Dutta et al., in review). Interviews lasted 45-60 minutes and were conducted in English. No financial incentive was provided to study participants.

Content analysis of the vaccine policy documents was completed separately, but in parallel with interviews and field notes of these interviews. The documentary evidence, combined with data from interviews and observation, allowed the researcher to counter threats to trustworthiness, such as reactivity, minimized respondent bias, and established credibility, while identifying CE themes and CE-related enablers and barriers.

A final step involved convening a follow-up meeting with participants as a group in December 2018 to present and verify study observations. Some participants invited their work teams to participate during the discussion and three participants, invited the researcher to meet them separately in January 2019. There were no appreciable changes to the findings based on the feedback.

Coding and Data Analysis

A deductive, thematic approach informed by the SEM framework initially was used to identify recurring and emerging themes. This was followed by a clustering of data into nodes and sub-nodes (Hsieh et al., 2005; Elo and Kyngäs, 2008). A priori coding included SEM levels and barriers/facilitators of CE. CE enablers and barriers for vaccination were then classified into all the SEM levels.

Thereafter, line, sentence, and paragraph segments of transcribed interviews, policy documents, and field notes were reviewed repeatedly to identify barriers to and facilitators of CE. Two additional and independent researchers coded a sample of 5 interviews and 2 policy documents to assure study rigor. A coding conference was held to identify and negotiate coding discrepancies. Categories with coding differences were addressed and re-defined through iterations until a consensus of 90% was achieved (Smith et al., 2000). The preliminary codes helped the coders integrate concepts already well known from the extant literature (Andersen, 1995). Care was taken not to compulsively fit data into predefined codes, though a 'start list' (Miles and Huberman, 1994) allowed new inquiries to benefit from and build on previous insights.

The concepts identified were reintegrated into themes, which now provide the structure for the study results. This led to a form of pattern recognition, with emerging themes/nodes becoming the categories for analysis (Fereday and Muir-Cochrane, 2006), and contained barriers and enablers for CE with 10 key underlying factors. All the 25 interviews and 24 documents were re-coded by the lead researcher using this finalized instrument. Nvivo 12 (QSR International, Melbourne, Australia) software was used to organize the data.

Results

Twenty-five vaccine decision-makers participated in the interview. Of them, two held Secretary-level positions, the highest office at the MoHFW for the UIP. Seven participants from technical and research institutes under the aegis of the MoHFW were responsible for vaccine

policy, operational guidelines and program formulation and approval, vaccine supply and cold-chain management, and certifying ethical conduct of vaccine clinical trials. Participants (n=3) from three UN organizations oversaw vaccine surveillance, uptake through social mobilization, and training of local stakeholders. Immunization heads in donor organizations (n=3) led strategic partnerships along with the MoHFW and ensured vaccination funding. Four technical heads from three multi-country, multi-partner projects, and six country-leads of non-governmental organizations (NGOs) collaborated with the government, donors, and technical partners in ensuring achieving the UIP goals or conducting the clinical trials (Refer to Table 4 in the earlier chapter).

Twenty-four vaccine policy documents were identified and reviewed for this study. Two documents on social mobilization and communication, and one on partnership, were published by UNICEF and CGPP - a multi-country, multi-partner initiative to strengthen in-country efforts in sustaining the polio eradicated status of India, and GAVI, the Vaccine Alliance - a public-private global health partnership to increase access to immunization in GAVI-eligible countries. More than half of the documents (n=15, 62.5%) were published during 2015 to 2018 and were vaccine-specific operational guidelines introduced during those years by the Ministry. Depending on their content, the documents could be classified into five categories: Policy and program review documents (n=3, 12.5%), vaccine and program-specific operational guidelines (n=7, 29.1%), Frequently Asked Questions (FAQ) booklets for communities and community-level stakeholders (n=3, 12.5%), Adverse Event Following Immunization (AEFI) documents (n=3,

12.5%), and Social and Behavioral Change Communication (SBCC) and social mobilization related documents (n=8, 33.3%). An overview of the documents reviewed is given in Table 7.

[Table 7]

Narratives of the elites and content analysis of the vaccine policy documents identified more CE barriers than facilitators at all the SEM levels. The outcomes are summarized and shown in Table 8.

[Table 8]

Policy-level CE Facilitators

At the policy level, there were 2 CE facilitators and 5 CE barriers. Enablers included the increasing political will to enact CE and elite intent for bottom-up (community-driven) CE measures. This was expressed as a desire to interact with and engage communities during the introduction and successive roll-outs of four new vaccines under the UIP between 2016-2018, and piloting of contested vaccines like Human Papilloma Virus (HPV) vaccine in three states. Some spoke about this as current behavior while others reflected on the evolutionary bi-level teaching and learning processes that took place:

> *"..introduction of any vaccine in the State has never been a challenge. We always go to the community and have media campaigns, we go to the people and have interpersonal communications. We use all sorts of communication channels to make people*

understand what we are going to introduce and give to their children to protect them from certain diseases."

"First the schools were not so involved, but then Karnataka showed us the way (that) the schools are involved and we improved our strategy so that in the next phase the school, teachers and students are involved in a big way. This was an example where we did mid-term corrective evaluation. That is why I am saying that involvement of the community is very important."

More than half of the participants cited that direct contact between the decision-makers and communities facilitated CE. This contact could take place in a variety of ways such as direct engagement in person or even by email:

"Because our email IDs are there on the website, emails (stating that) *'my child has not been approached for full immunization,' or 'this vaccine is not available in my community' come to us, or directly to the Minister or the Prime Minister's Office; and then we reply."*

Participants recollected regular home-visits by the national-level decision-makers during the National Polio Surveillance Program (NPSP) as a CE enabler. NPSP was a campaign of the WHO and MoHFW initiated in 1995 to ensure polio eradication through house-to-house poliovirus vaccine delivery:

"When you go to a village, there would be lots of people who would hang around for curiosity sake. So, then we sat with them and asked if they wanted to talk with us. We would ask, why the children were not getting immunized. Then they would ask what the harm is if they did not get immunized? Or what is the advantage of getting immunized? So we would sit down and answer their questions."

Policy-level CE Barriers

Most participants acknowledged decision-makers' complacency with a 'social mobilization' approach to vaccination uptake, implying that this was preferable to the work of *'doing real CE.'* These participants identified a dearth of '*institutionalization of CE,'* which they thought had reinforced the distance between the decision-makers and communities.

> *"They* (implying Government) *only focus on vaccines. If they work on vaccines I am very happy. Which means that we have high level political will. We have the Prime Minister tracking vaccines and everything on community engagement should be happening now. But it is not happening, that is for sure."*

Notably, most participants critiqued the abovementioned community and home visits as 'ad-hoc CE', clustered during NPSP, which was designed to be delivered through home visits, or undertaken during vaccine introductions, especially in pockets of disease outbreaks to mitigate communities' vaccine-and vaccination-related anxiety. One person labelled this as *'dousing the fire'* rather than ensuring sustainable CE and another quoted below denied any direct and empowered communication between the communities and the decision-makers.

> *"Communities need to be given a platform where they can share their viewpoints. But it is not there. If this were there, these leaders and policymakers would need to think twice. There is no direct channel of communication between the community and the policy maker. These public responses is thought of when there is an adverse event, like in Tamil Nadu recently for M-R vaccine campaign."*

Two participants commented on the lack of any CE indicator in national-level datasets, or any studies examining the CE effectiveness as barriers to strategically defining, planning, implementing, and assessing CE.

> *"The demand side barriers are very special in and of themselves and they require engagement and they require understanding. It cannot be done with one coverage evaluation survey done six years ago which says 40% of this* (lack of immunization) *is because of demand. I cannot unpack that. I can do nothing with that information."*

More than half of the participants reported the lack of any dedicated policy guideline document on CE. This included the absence of village-level communication plans. However, a few policy documents, such as Communications for Development by UNICEF, Strategy for Hard to Reach Populations, and CORE Communication Strategy, were cited by participants as being the nearest to any CE strategy. Notably, there was no evidence of any community involvement in formulation of these documents. Further, while decision-makers mentioned translation of these documents to the national language (Hindi) and other scheduled languages spoken in different States of the country, there was no evidence of these documents being available in any local dialects or mother-tongues.

Community-level CE Facilitators

Publication and decentralized dissemination of targeted SBCC materials from the national-level to the states, districts and local levels was identified as the only CE enabler at the community-level. Specifically, these activities facilitated community-level interactions among those with high vaccination resistance and low vaccine coverage for improved vaccination decisions. Participants described a variety of interpersonal and media messages, reminders/prompt messaging through mobile phones and WhatsApp, door-to-door canvassing, and strategic 'miking' (the use of itinerant megaphones) informing the dates for specific

vaccines and urging communities to complete the vaccination schedules. These were mainly completed by frontline health care providers and local role models who include religious, political, and trade leaders among the rural communities, and migrant laborers like brick-kiln workers, those belonging to minority religious groups like Muslims, and Scheduled Castes and Scheduled Tribes -the last two being constitutionally designated as historically disadvantaged people.

> *"See, the communication materials are developed in English and in Hindi by us and then it goes from the Ministry to the state and then they modify it. If they think that something is to be added or deleted or modified."*

Several policy documents reiterated the need to address vaccine-related structural and cultural barriers in order to mobilize vaccine hesitant and resistant communities. This was evident from titles like *'FAQ on Immunization for Religious Leaders, Media Persons, CSOs, Influencers & Other Stakeholders'* and sections in the *'Social Mobilization'* document like *'Devote time to the selection, training, and support of community-based outreach workers*'; *'Advance the participation of women as social mobilizers, vaccinators, surveillance officers, and leaders in polio eradication efforts'*; and *'Involve children in campaigns to help counter 'campaign fatigue'*. A quote from the Social Mobilization document can explains tailored CE interventions:

> *"In group meetings called Ijtemas, held separately for men and women, both male and female leaders use exhortations from the Koran and the Haddiths to stress the obligation of parents to protect the health of their children."* (Source: Social Mobilization: Lessons from the Polio Project in Angola, Ethiopia, and India, September 2012).

Review of vaccine policy documents revealed use of group-based dialogues, dyadic approaches to vaccine-related information sharing, and engagement of community champions for information and communication dissemination.

Community-level CE Barriers

Most participants mentioned various power-relations linked to class, caste, religion, and gender relations within communities, which, though not related to vaccinations, impeded community health provider interactions and affected communities' vaccination decisions. Three decision-makers narrated such incidents, which are paraphrased as follows:

- *An incident where the vaccination camp was organized closer to the higher caste person's house leading to lesser turnout of the lower caste communities to this vaccination camp; second was a case of adulterated yellow potable water from a Government installed hand-pump when adjoining communities became suspicious to any Government initiatives, including vaccinations; and the third was of a weaver in Uttar Pradesh State who witnessed the loss of traditional livelihoods among the community after the advent of cheaper Chinese yarn, which instilled the fear that anything 'foreign' aka vaccines would systematically jeopardize their lives or livelihoods.*

Another participant reported:

> *"I see an obsession with immunization, which may not necessarily mean community engagement, unfortunately. It may mean loud noise. It may mean perverse incentives. We will not give you cheap ration because you did not get your immunization. It may mean many things but the point is that what is the goal? The goal is to increase the immunization coverage. Community engagement might not be the prime to the administration....and maybe it is not so bad, but it is not the best way to engage with your community."*

Some participants indicated that these inequities were expressed in other ways, suggesting that community members' choice or decision to vaccinate was subjugated to the act of doing so.

> *"From the community point of view, I think both the Government and other stakeholders are talking down to them. I think that needs to change. In that arena, I do not think that we have progressed much in the last 10 years. We are still not telling the community what these* (vaccines) *are about. We are only telling them that they need to get them."*

Another kind of power-related barrier was the frustration expressed by heads of NGOs who felt that the *'Government is trying to clip their* (NGO's) *wings.'* These participants recommended an *'integrated approach'*, though it was unclear how it would impact CE interventions or bolster linkages between communities and health facilities.

While interviews revealed community level and community-decision makers power-equations, these were not articulated in the policy documents. Documents were mostly preachy with little or no recommendation of 'how' to use the community action cycle, CE quality improvement approaches, or cultivating an enabling environment for optimal CE practices so that vaccination services are effectively utilized. For example:

> *"Enabling processes for rapid decision-making to allow building alliances and partnerships, both national and global, and for support to agencies for diffusion of the technologies into the social systems, should be in place."* (Source: National Vaccine Policy, Ministry of Health and Family Welfare, 2011).
>
> *"This will help facilitate more comprehensive interventions in participatory planning for program activities, closer interactions with the communities, convergence and rationalization for undertaking broader child health initiatives."* (Source: UNICEF, Evaluation of Social Mobilization Network (SMNet) - January 2014).

Furthermore, the language, especially in the AEFI documents, appeared to have a disempowered conceptualization of communities as beneficiaries, which has the potential to exclude disadvantaged groups from vaccine policy and vaccination initiatives too. For example:

> *"….engage and convince communities after India achieving 'polio-free status' especially mothers/caregivers on the importance of vaccinating their children again and again for and during polio campaigns."* (Source: Intensification of Routine Immunization: Communicational Operational and Technical Guideline, MoHFW, 2012)

> *"…Visiting the immunization site, vaccine storage point, residence and locality of the patient and the treatment centers."* (Source: Intensified Mission Indradhanush, Operational Guidelines, 2018).

Notably, there was an abrupt silence or change of topic when questions on contested vaccines like HPV were asked, which could also be a potential CE barrier. When participants were asked about the introduction of HPV vaccines, their responses were mixed. Five participants mentioned successful introduction of HPV vaccines in states and credited it to the intensive training of frontline healthcare workers. However, several others exhibited discomfort when plans for HPV vaccine introduction were solicited. One person changed the topic, and two other participants mentioned that they were not holding the office or that they did not work on HPV vaccines after demonstration projects were stalled in 2010. Further, there were no operational guidelines for HPV vaccines explaining its phase-wise introduction, which, in itself, could be a CE barrier, considering that HPV vaccines cater to a unique population (adolescents) compared to the general childhood immunizations provided under UIP.

> *"……like you saw in HPV vaccines.* (For) *all vaccines the same public voice for policy change is not there, unless there is a problem or AEFI etc. And then also, policymaker thinks how to stop the immediate emergency, but not to empower the communities."*

Organizational-level CE Facilitators

Participants and policy documents highlighted partnerships with multilateral organizations such as GAVI, WHO and UNICEF, and inter-sectoral technical groups like 'Mission

Steering Groups' to promote and leverage CE. Such partnerships and Task Forces at the national, and state-levels promoted and advanced participatory approaches of bilateral and global partners.

> *"Mission Steering Groups are people from various Ministries who determine the feasibility of implementing the recommendation, which includes elaborate and transparent processes."*
>
> *"…when we talk of community engagement there are two platforms, one is State Task Force on Immunization and another is the District Task Force on Immunization, who have regular meetings."*

Participants, especially from the Ministry, also acknowledged local youth organizations, namely National Cadet Corps (NCC), Nehru Yuva Kendra Sangathan (NYKS), National Service Scheme (NSS), and Rotary International, who partner and collaborate with the government to achieve the vaccination target of reaching every child. Most of these were volunteer-based, except for the Rotary Club, whose *'SOP on Engagement of Youth Organizations and Rotary for Immunization'* was identified.

Participants expressed their reliance on these local organizations, and credited them for undertaking social mobilization activities along with the ASHAs and AWWs in their respective areas to ensure full immunization of all children. They were also acknowledged as being involved in the district task force meetings, organizing advocacy awareness and infotainment programs alongwith public practitioners and local political, religious, and trade leaders, and regularly disseminating information through local media both using electronic and print mediums for vaccine-related awareness to support routine immunization and vaccination campaigns. The below quotes elucidate this:

"Very recently Government of India has signed a MOU with Rotary. Actually, Rotary was previously involved. Rotary will help us with community demand etc. in Routine Immunization."

"The CBOs and CSOs: They are helping us to take our messages down to the community. Some of them are involved in community education, both in rural areas and urban slums, so that they are forthcoming to get the vaccines."

While the virtue of partnerships with local-level NGOs, and CBOs was equivocally acknowledged in the National Vaccine Policy, it was perceived as a strategy for vaccine development and outreach, rather than for CE:

" ..*several examples where product development have taken the PPP route and have resulted in shortening of the time frame for vaccine development, such as the Meningococcal Meningitis Vaccine Initiative (MMVI), where the product was produced in India with multiple partners, met international standards in quality, was exported to and used in Africa. The model has been instrumental in indigenously 116E Rotavirus vaccine being developed with effective collaboration between Indian & US academia, and Indian vaccine industry in partnership with PATH."* (Source: National Vaccine Policy, Ministry of Health and Family Welfare, 2011).

Organizational-level CE Barriers

Participants highlighted the fact that efforts to collaborate with local groups like youth organizations, women's SHGs, CBOs, and faith-based networks generally functioned without any monetary incentive or salary. Some participants mentioned refreshments/mementos offered to the NCC, NYKS, and NSS members during the sessions by the District Magistrate as incentives in order to acknowledge their efforts toward 'good' vaccination uptake. Here the assumption was that effective vaccination uptake was equivalent to successful social mobilization. Even so, this approach was rarely considered enough to motivate or appreciate the 'volunteers' appropriately by many participants, and was viewed as a barrier to sustaining these partnerships.

> *"These felicitations* (providing certificates during a village gathering) *were given to the local headman for more than 90% vaccination coverage, acknowledging their contribution. But there was no monetary incentive."*
>
> *"No, we do not have any formal MoU kind of a thing with these CSOs and CBOs. They come and they have been working with us."*

Neither responses nor documents identified any CE gold standards or cited any specific partnership strategy which showed improved satisfaction or positive relationships between the system and the communities.

Interpersonal-level CE Facilitators

Participants described about a noteworthy evolution in vaccination messaging tone and indicated that this was a CE enabler. There was a change from *'vaccinate your child'*, *'Don't forget vaccination your baby must get,'* to a message of *'Be wise, fully immunize your child,'* published in the National Health Portal and all the community-facing SBCC materials like banners, leaflets, and advertisements in the mass-media. This includes the current tagline '*5 saal 7 baar, Choote na teeka ek bhi baar'* (depicting the importance of routine immunization with the message that a child should be immunized seven times in first five years of its life), which is endorsed by celebrities in every immunization advertorial. According to participants, the earlier frame of vaccination as a parental onus reflected the top-down nature of vaccination delivery, rather than engaging with communities, while the current messaging reflected the government's realization that it must clarify the difference between vaccination and immunization, especially at a time when communities might be overwhelmed with several new vaccines being introduced under UIP.

Another participant explained the significance of the 'Mission Indradhanush' logo depicting seven colors of the rainbow: providing vaccination to seven vaccine preventable diseases diphtheria, whooping cough, tetanus, polio, tuberculosis, measles, and Hepatitis B.

> *"Have you seen the logo of Mission Indradhanush, the rainbow, an umbrella of seven colors? It means seven colors of the rainbow and aims to immune the children from seven vaccine-preventable diseases."*

This messaging change was related to participant recognition of the value of awareness generation about immunization and IMI using social media like Facebook and WhatsApp as a CE facilitator, especially in rural areas. They mentioned that social media platforms generated attention about vaccines among the rural, peri-urban, and hard-to-reach communities.

> *"Like today there is a social media strategy after M-R (Measles-Rubella) campaign. Today Health Ministry is using its Twitter account and putting in people to tweet. What has Twitter to do with Health Ministry? But yes, it is becoming important. How do you send messages through WhatsApp so that the messages reach? Earlier messages were through texts. Who is there to read your texts? Who is there to forward your texts? Nobody is interested. So, messaging is getting more and more creative."*

Considering the predominantly patriarchal society in India, IPC by healthcare workers targeting mothers-in-law and husbands was considered a CE enabler, correcting myths and misconceptions about vaccination and counseling them to 'allow' mothers to vaccinate their vaccine-eligible children.

> *"…mostly the men talk and they will not listen. So, we went to the barber's shops. That was the only place where the men used to be shut.* (Our Communication personnel) *gave some danglers (wall hangings) to the barbers. Barbers have associations whom we*

approached. There are two kinds of barbers, who have fixed sites in shops/salons or they go to your house and cut your hair. So (Our Communication personnel) *designed their aprons with messages for immunization. And then we taught them to talk to their customers around immunization of the latter's child."*

Inter-personal level CE Barriers

Participants indicated that Training of Trainers (ToT) for the ASHAs, ANMs and Anganwadi Workers, such as the Boosting Routine Immunization Demand Generation (BRIDGE), sponsored by UNICEF, was a facilitator of CE because they taught inter personal communication skills (IPC). That said, they also indicated that such trainings needed more time investment to yield quality results, posing this as a potential barrier.

"If you really look into BRIDGE training, you are building somebody's interpersonal communication capacities. Private companies invest huge amount(s) where they train their marketing personnel how to go and talk to somebody. Whether I am going to talk to the business executive or whether I am going to sell from door to door, that engagement strategy is a very critical and we need to invest more time and energy for that (in the BRIDGE trainings)".

One participant noted that missing out on SBCC materials for certain sub-populations, or not having any family-centric SBCC approach was a major barrier to CE:

"Wives of men based in the Middle-East often did not get a timely affirmative vaccination decision, mostly leaving their children unvaccinated. We need to develop some strategy for this group"

Review of the policy documents yielded several barriers to effective IPC and SBCC with the communities. Contrary to the expressed enthusiasm of participants about the use of social media for vaccine messaging, none of the policy documents highlighted the increasing proliferation of social media in rural and semi-urban areas. Most participants drew a relationship between communities' negative vaccine experiences, either due to side effects or

vaccine-related rumor and misinformation. They also acknowledged that the relation between vaccination experience, vaccine knowledge, and rumors is complex, and the government lacks any rumor management strategies, especially when they are spread through the social media.

> *"So that kind of engagement was very new to the Government and to the partners because there is already a negative atmosphere created at variety of levels, even before the introduction of the vaccine and that has a direct impact on the community."*

The immunization FAQ booklets, though designed specifically for separate stakeholders, were notably similar. For example, the content was same for the following two FAQ documents:

- FAQ on Immunization for Religious Leaders, Media Persons, CSOs, Influencers & Other Stakeholders, 2017
- FAQ on Immunization for Parents & Caregivers, 2017

In addition, while the 'FAQ on Immunization for Health Workers and other Front-line Functionaries' booklet mentioned herd immunity, it was not mentioned in documents for the communities. The AEFI-related documents emphasizing '*managing communication in the case of an AEFI'* or *'handling a rumor regarding an AEFI,'* contained several technical concepts needing demystification like: *'immunization error related reactions,' 'immunization anxiety related reactions,' 'verbal autopsy form.*'

Individual-level CE Facilitators

There were several examples of participants recommending institutionalized support for more participatory CE, but no examples of anyone actually engaging with communities at an individual level. Two examples of individual interfaces were: home visits for polio vaccination (cited by participants) and investigation of serious cases post-vaccinations (mentioned in the Midterm Review Multi-Year Strategic Plan 2013-17, and AEFI documents). But since, by design, the polio eradication campaign (NPSP) was a house-to-house delivery program, and AEFI cases mandated an individual-level inquiry, these are not appropriately categorized as individual-level CE enablers. Only one participant cited 'doing an extra bit' in an individual capacity, which could be considered closest to an individual-level facilitator. However, it was for vaccination uptake rather than any CE outcome:

> *"…delivering the vaccine last mile is one of the major challenges. There were two places where the vaccine was transported through helicopter. First time Government of India gave that fund. Although the beneficiary children were only 15 but we argued with the Government. I personally argued from UNICEF that if you say that 100% children are to be immunized somehow you have to send the vaccines to that place."*

Individual-level CE Barriers

The policy-level examples of decision-makers visiting the community or directly engaging with the community via email also figure at the individual-level. That said, participants mostly discussed the use of individual-level actions driven by policy decisions and experienced at the individual or community-level. An example was of the hiring of a *'muscle-man'* to *'convince the communities to vaccinate their children.'* Interestingly, participants positioned this type of individual-level 'coaxing' as the only way to counter the demand-side barriers to CE such as: communities' vaccine resistance, ignorance, lack of literacy, misinformation by target population (adolescent, adult), religious perception (Muslims fearing that vaccines will sterilize

their children, or something which is considered against their religious order), doses (confused between one-dose, multiple-doses, and not clear about the concept of 'full immunization'), logistics (remembering to get the vaccine), and relationships with the local health provider. One participant said:

> *"I would like to talk about the people who are not coming forward. This 10% population are the ones who are resisting. That is the population that needs to be taken care of, reached, or taken out of their home to reach the immunization sessions."*

Summary of the Participants' Follow-up Convening Meeting

The participants' convening meeting (full-day) was held in New Delhi on December 19, 2018. Three participants who could not make it to this meeting met the researcher separately in their offices in January 2019. These meetings provided the opportunity for a review of observations and verification of results. Participants overwhelmingly agreed with the reported results and also worked together to develop an operational definition of CE while also had recommendations to improve CE in the vaccine arena.

A comprehensive, and aspirational CE definition was formulated consultatively, and its importance was reiterated by participants and their working teams, most of whom managed Departments like Communication, and Vaccines Delivery:

> *"CE is an upstream policy imperative, rather than downstream interventions to build trustworthy relationships between vaccine decision-makers and communities. It involves demystifying science and transparent communication for empowered community agency. This would enable communities to critically analyze vaccine related myths and misinformation and enable knowledge co-production in building community-sensitive vaccine policies and programs. (CE) is incumbent to sustained political-will and resources to ensure evidence-informed, tailored, vaccine policies and programs, providing*

equitable, quality, and tangible vaccination and capacity building benefits to community members."

Discussion

This study was the first to identify CE barriers and facilitators related to vaccination in India using the SEM framework. Triangulation of data through a staged process captured CE's governmentalization during the Decade of Vaccines in India. Similar methodological approach by earlier researchers using organizational documents and interview transcripts yielded enduring results like: identification of overarching themes on performance in the nursing practice, technology-enriched curriculum, and a grounded theory of corporate turnaround, respectively (Fereday and Muir-Cochrane, 2006; Angers and Machtmes, 2005; and Pandit, 1996). It also helped to understand the varied experiences of decision-makers in implementing CE for vaccination, while investments, intensification, and institutionalization were being recommended for, to realize the mission of MI and IMI (Malterud, 2001; Braun and Clarke, 2006; Lewis and Ritchie 2003). This study directed attention to nuances like lack of any CE-specific strategic document for vaccines, absence of dedicated staff to establish scientific mechanisms of CE in policies and programs, and a culture of silence for CE strategies for contested vaccines like HPV in India.

Vaccine decision-makers' expressed appreciation for the usefulness and timeliness of the study, both retrospectively and prospectively, to understand past CE challenges and successes and to appropriately plan for future vaccine introductions and roll out. The findings therefore contribute to two major discourses: the community empowerment discourse and the

systems discourse of CE. That said, due to various ongoing incidents of political activism and conflicts of interest between the vaccine provisioning authorities and the communities, decision-makers were cautious, to the extent that it was challenging for me to seek entry to the Health Ministry on certain days for data collection purposes. This was because of multiple reasons. At one end, the MoHFW had shelved the introduction of the HPV vaccine after representatives of a political party urged the Prime Minister not to introduce the vaccine because it '*brings ignominy to the scientific community in the country and sells the country to vested interests'* (Outlook Web Bureau, January 10, 2018), while, at the same time rations (under the Public Distribution System of a Government scheme) were being denied to families until they vaccinated their children (Dabas, The Times of India, January 2018). Fortunately the researcher's, prior knowledge of the sector and familiarity with the decision-makers facilitated circumventing these challenges with data collection (Hoch child, 2009).

In other studies, vaccine decision-makers from Rwanda and Bangladesh have identified upstream drivers for effective vaccine introduction and rollout including research findings on vaccine-preventable diseases, participation of technical committees and professional bodies, political issues relating to disease outbreaks, and pressure from international development partners (Gatera et al., 2015; Uddin et al.; 2013). These studies have characterized CE within the commonly cited range: tailored vaccination strategies to the local context, engaging community health workers and local stakeholders for decentralized vaccine outreach, and community meetings to deliver information, about vaccination. However, such approaches reduce the community's identity as 'vaccine recipients' with little or no agency to make

empowered vaccination decisions or invigorate their social capital for pharmacovigilance (Lindström, 2008). That said, this study also identified an overarching utilitarian conceptualization of CE by decision-makers (Dutta et al., under review), which, at times, seemed conflicting with their stated desire. For empowered and discerning communities demanding vaccines, and with policy documents without sufficiently detailed procedures to achieving such an aim. Here, we argue that this might not reflect a lack of effort by the vaccine decision-makers to address CE priorities. Rather, it could be function of the complexities involved in standardizing CE strategies for a diverse country like India, which has an annual birth cohort of 27 million [vaccine eligible children].

While there did not appear to be an overt imposition of specific CE requirements by donors, its pre-determination to a considerable extent in accordance with government-determined guidelines reflected some kind of a pressure on the implementing NGOs and CBOs. In this process, the latter could be mere implementers to the CE mandates, rather than becoming amplifying voices (Kawachi, 1999).

Collaborative partnerships, are not a new means of improving community outreach for vaccination in India. However, challenges related to power differentials, timeliness, and accountability, innate to these partnerships need to be documented both in rhetoric and practice (Popay and Williams, 1998). For example, Lo et al.,'s work [partially] associates late engagement of HIV stakeholders in PrEP research to its implementation challenges. They claim

that early and deliberate engagement facilitates CE design and conduct of vaccine trials, and decreases likelihood of therapeutic misconceptions (2015).

CE barriers identified in this study mirrored results from other evidence suggesting that top-down interventions, and engagement behaviors reinforcing power differentials, often are exacerbated by the community's poverty and livelihoods crises, negative beliefs about vaccinations, and poor treatment of communities by healthcare workers and authorities (Favin et al., 2012; Larson et al., 2015, McQueen et al., 2015). Therefore, poorer, rural, minority communities, and women, were presented as the most conservative toward, suspicious of, and resentful to vaccines and vaccine provisioning authorities. Studies by WHO SAGE explain this as 'covert resistance by communities' (Hilber et al., 2016; Shankar and Dutta, 2010), Betsch and Böhm identify this resistance as 'reactance' among communities to regain their constricted freedom of choice (2015), and other scholars have explained this as community members' suspicions about the 'sudden interventions' by the authorities (Chaturvedi et al., 2008; Mavimbe et al., 2006; Oluwadare, 2009; Schwarz et al., 2009). Here, we contend that the Hard to Reach Population Strategy is area-based initiative building Health Action Zones (Powell and Moon, 2001), focusing on the poverty of places, and might miss on the relatively deprived families who might live outside these areas. While most decision-makers and policy documents in this study dismissed communities' vaccine resistance as 'not vaccine related,' vaccine communication needs to address the social construct of vaccines. Specifically in the caste, class, and patriarchal context of India, community's disapproval of government policies or paternalistic healthcare providers could be mostly dictated by upper class and caste-group

people or men, while it is the poor, minorities, and women who are often blamed by the authorities as being negligent to their children's health. Further, intersectionalities and predicaments among the socio-economically disadvantaged are important to consider, as these communities try to negotiate between social pressures and preventive health, especially because subsistence typically takes priority over health in general, and immunization in particular, among these populations (Chaturvedi et al., 2008, Merten et al., 2011).

Strategic CE needs to be done with vaccine gatekeepers. Studies suggest that this might enable access to potential vaccine users via those who interact with communities in their local dialects, while also empowering communities to make informed vaccine decisions by having debates between vaccine supporters and gatekeepers (Brian, 2016; Dutta and Lin, APHA, 2017).

Though there was an overarching recognition that successful CE required demystification of vaccine-related knowledge among the community, examples in practice consisted of information sharing on vaccines, their side effects, and vaccine schedules (Earl, 2001; Seeber et al., 2015; Noah, 2002). Kilpatrick (2009) fears that such biomedical training models can impede participatory approaches because trainees might be attracted to utilitarian gains rather than empowerment approaches to CE. This triggers to question the communities' capacity-building on the science of vaccines. This is because most reported cases follow a minimum disease symptom post vaccination, which should rather increase the community's trust on vaccine efficacy, because of the understanding that the occurrence of the disease can

only provide life-long immunity, and that is how precisely any vaccine works (Bisht and Coutinho, 2000).

Furthermore, the element of herd immunity needs demystification (Stapleton, 2015) to enable communities understand the concept and assuage parental fear especially for babies who are too young to be vaccinated or immuno-compromised children, who are the first potential victims of low vaccination rates (Rapaport, 2018). Plotting of vaccination opposition in a timeline against vaccine introduction could help identify sub-population-based vaccination resistance patterns and design interventions accordingly.

Research from developing countries has reported mixed findings on the choice of the form of IPC and SBCC for vaccine sensitization, ranging from community radio, and pictographic training materials, to prevention messaging through the television (Jackson et al., 2017). Growing economies like India need to make community-level investments reiterating vaccine benefits rather than building on threat perceptions. This can be done by (i) sensitive tailoring of innovative messaging using folk infotainment methods like sharing success stories of complete eradication of smallpox, and the near eradication of polio globally, and its eradication in India; (ii) simplifying technical differences, such as vaccination (which could be getting an injection or nasal spray or oral vaccine) and immunization, meaning receiving all the dosages of the vaccine and becoming immune to a disease, and (iii) translation of vaccine messaging to mother tongues and dialects because almost 200 of them, which are variations of the official Indian languages, are the predominant languages used by the indigenous and rural populations. With

the proliferation social media messaging, the usefulness of vaccine-related information needs to be weighed against rumors and misinformation spread (Alter and Redlener, The Hill, February 2019).

Conclusions

This study analyzed the methodological challenges and informational benefits associated with interviewing elites while conducting qualitative research, especially when the policy processes being studied play out in real time. A limitation of this study was that the factors affecting CE in a specific setting might not be interpreted correctly based on information from national-level decision-makers and policy documents. To address this, Dutta regularly summarized and fed back my interpretation to the participants during the interview to seek respondent validation.

The findings from this study strongly indicate the need for evidence-based approaches to promote CE, such that the pursuit of health equity, which is central to vaccine introduction and roll out, is realized. Future CE barrier studies should identify key outcome indicators of CE based on a critical awareness of the history and nature of relations between communities, vaccines, and vaccine-providing authorities in diverse cultural, economic and political contexts. Immunization program evaluations need to include CE needs-assessments, map sub-population based expressions of vaccine hesitancies, and conduct formative evaluations of CE outcomes at all the social ecological levels.

CHAPTER 6

CONCLUSIONS AND NEXT STEPS

In this study, the 'whole community' approach was applied to understand conceptualization, barriers and enablers of CE by national-level decision-makers and policy documents, in the case of immunization in India. This was done not only because it is the most inclusive definition of community encapsulating the full spectrum of individual community members as well as community-based organizations, but also because it is dynamic concept that changes with shifting environmental, socio-economic and political factors. Subjectivity was somehow inevitable given the diffuse nature of the concept, and the lack of more straightforward indicators of community engagement (Gallivan et al. 2012).

The uniqueness of this study and the differences in its outcome compared to other recent work (Pramanik. et al., 2018; Gopichandran, 2017; Nagar et al., 2016) which could be entirely due to the differences in the study objectives mostly looking at community-level demand-side factors which impacts vaccination utilization, timeframe, study sample, and the measures used.

Limitations of Study Design and Analysis

A limitation in this study was the reliance on self-reporting by elites. Memory varies, and there is deterioration of the reliability of memory over time (Tourangeau, 2000). However, this study reports CE over the Decade of Vaccines and there was no other better way to obtain the data

than collecting it from national-level vaccine decision-makers. Also, triangulation of the findings of the narratives with review of policy documents and member check-in meetings, was another way to address this limitation.

One could question the social desirability concerns in the study, wherein study participants might have responded in explaining their roles because 'doing CE' is socially desirable. Social desirability was addressed by keeping the name and affiliation of the participant confidential and not ranking any of the CE practices as 'best practice' over another. Also, the researcher's knowledgeability of the context of CE and vaccines in the country minimized skewing of the results.

A limitation was the lack of any measure of fidelity toward replicability and maintenance of standards in CE implementation. Again, there was no measure of frequency of use of a particular CE strategy. Though regarded as important by evidence-based practice researchers like O'Hare (2005), fidelity was not addressed in this study, thus conclusions concerning fidelity to practice CE standards are unavailable.

Generalizability beyond the sample itself was limited to the national-level vaccine decision-makers, and the vaccine policy documents. Because of this, the results of the study can be generalized to limited national settings where vaccine provisioning and governance, and CE implementation are similar to India.

Strengths of the Study

The main strength of the study lies in the conducting elite interviews of those who have been in the vaccine decision-making role for a decade or more. This allowed enriching the research with a variety of CE conceptualizations and understanding its evolution. The political-will of vaccine decision-makers' was obvious, and can serve as a marker of influence to allow research, education and practice of CE within the vaccination context in India.

The study invigorated the researcher's confidence in 'discovering' newer routes to establish linkage and relationship with the elites: for example, beginning a conversation with a simple personalized greeting, rather than hurrying through the study instrument was helpful. Acknowledging another senior colleague who might have helped in connecting to the study participant was also useful. With extremely busy schedules, almost all participants received phone calls, or had brief interactions during the interviews. Attentive listening and reminding the participant of where s/he had left, not only facilitated continuing the conversation, but also helped in reconfirming what s/he was mentioning. Tailored use of social media like Facebook Messenger, or WhatsApp, for select participants who were comfortable with it helped in connecting more effectively and alluded some of the limitations of hierarchical, and centralized messaging. In the same breath, researcher's humility was utmost important to probe at the right places in the right way while also understand issues/areas where the participants were not too comfortable in answering.

Literature has noted that studies without using a particular theoretical lens has often led to conflicting and confusing results (Eccles, et al., 2005; Walker, et al., 2003). In this study, the adaptation of the hybrid of SEM and KFT to analyze conceptualization and implementation of CE through the Decade of vaccines in India, instead of personal cases stories (Rogers, 2003). The hybrid model allowed considering that there are variables at all levels from policy to individual-levels, which affect CE implementation. Also, the candid narratives of decision-makers, and support to convene a follow-up meeting, reinstated the hypothesis about leadership's positive intention to implement CE best practices for improved vaccination in India.

Implications of the Findings

Implications for Policy and Practice

The study results suggested intent and motivation of vaccine decision-makers to implement CE in the vaccine arena, who also came up with an operational definition of CE. This is an important predictor to exploiting opportunities for increased CE in the vaccine space.

The study findings highlighted that while vaccine policies and decision-makers in India have focused on vaccination uptake, planning, implementation, and improvement processes of CE have not been adequately reported. Decision-makers need for CE as a policy priority, including more practices of directly engaging with communities needs to be followed up and realized.

Similarly, there were convincing examples during recent times to train the front-line providers enhance their quality engagement with the communities by utilizing m-health and e-health technologies. In parallel, increased expressions of CE's practice effectiveness needs to be captured in vaccine policy documents. Gubernatorial notes need to reflect confidence, that is, the ability of the vaccine decision-makers to push for a CE strategy and implement it. Apportioned resources dedicated for CE monitoring system would facilitate in carrying out studies to understand CE's effectiveness rather than just tracking their implementation such that recurring instances of community backlashes and resistance might be prevented.

Recommendations for Further Research

Study participants narrated CE implementation as linear implementation models occurring in stages, especially during vaccine introduction and roll out. An analysis including time as a moderating factor of vaccine decision-makers' motivation to implement CE by social contextual variables might help mapping the CE evolution better. Toward that end, a longitudinal study design or a type of statistical analysis, which allows the use of time as a factor, such as using a structural equation modeling would be useful.

Another way could be to look at CE's equilibrating influence (controlling community outrage, currently by using restraints on certain facilities to communities or by counselling and encouraging their positive vaccination decisions). Future studies need to explore which CE interventions works best in gaining community confidence and in enhancing vaccination coverage over what period.

In addition, exploring CE in the nuances of intersectionalities, or the use of other theoretical frameworks, like Diffusion of Innovation can explain the relationship between CE interventions, exchange of information, and the adoption/utilization of vaccines as a product of non-adopters' modeling and imitating adopting peers.

Summary

Consonant with theoretical understandings and evidence, the process of CE implementation in India manifested evolution and a better acceptance among decision-makers though in the overall understanding and governance of CE several shortcomings were noted. This study underscores that: (i) improving conceptual understanding of CE by policymakers, (ii) having well laid out CE strategies and monitoring mechanisms, (iii) investing in frontline caregivers to involve with communities in a respectful way, (iv) creating spaces and structures for empowered interactions between the decision-makers and communities will improve CE interventions in making efficacious vaccines effective for populations who need them the most.

Strengthening community health worker systems, mobilizing communities to address structural and cultural barriers, addressing vaccine-provider behavior and improving the quality of community-health provider interactions, will bolster linkages between governments, local, private stakeholders and communities. While this might not be any re-invention, it certainly needs research activism to acknowledge CE as a policy imperative to mature and develop deeper rather than simply proliferate.

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TABLES

Table 1: Areas of community engagement and institutional mandate and support for the same Areas of community engagement and institutional mandate and support for the same
Levels of commitment to community engagement

		0	1	2	3
		Very Low	**Low**	**Medium**	**High**
(i)	**Mission Statement**	No mention	Undefined rhetorical reference	Community engagement is an element of academic agenda	Community engagement is central and defining characteristic
(ii)	**Involvement/Interest of Leadership in community engagement**	Apathy	Neutral	Philosophical intent with not much interest	Involves and interested to integrate and advance community engagement
(iii)	**Programmatic thrust for Community Engagement**	No Programs	Under-defined	Community engagement as a token element	Community engagement is central and integrated to each program
(iv)	**Processes and Community Engagement Outcomes**	None	Under-defined	Check-list activities and outcomes	Defined goals, intermediate outputs and final outcomes of community engagement
(v)	**Personnel for Community Engagement and his/her hierarchy in the organization**	None to foster volunteerism	Units exist but no specialized personnel	Various separate centers and specialized implementation personnel to advance community engagement	Community engagement Personnel for in a decision-making position
(vi)	**Resources and other Investment for Community Engagement**	No resources apportioned for community engagement	Managing Resources from other programs for certain community	Managing Resources from other programs to keep the	Apportioned resources for community engagement

			engagement events per donor commitment	community pulse alive	processes and events
(vii)	**Relationship and Communication with Communities**	Do not exist	Indirect relationship with few influential people as brand champion/community advocates	Communities as beneficiaries and target population	Communities as partners and stakeholders in program and advisory committees of the program

*** Adapted from Barbara A. Holland, 2001. “Analyzing Institutional Commitment to Service”. Michigan Journal of Community Service Learning, Vol. 4, Fall 1997, pp. 30-41

Table 2: Measures of community engagement factors for vaccination classified into SEM levels

SEM Levels	CE facilitating factors in the vaccine space
Policy-level factors	• Evidence of strategic engagement with communities during vaccination intervention and campaign planning and implementation written in policy documents. • Examples of political-will for CE especially among populations who needed it the most cited by study participants.
Community-level factors	• Evidence of class, caste, gender, rural versus urban related power-structures affecting CE between communities and authorities. • Examples of negotiations between the community and the vaccine providing authorities, like *'build the road then we will take the vaccines'*.
Organizational-level factors	• Evidence of formal or informal partnerships between national and local stakeholders (religious leaders, clubs, women's groups) who influence positive vaccination decision among communities.
Interpersonal-level factors	• Evidence of transaction of Social Behavior Change Communication (SBCC) and communication between healthcare workers and local stakeholders and the communities to address vaccine related myths, rumors, and mis-information.
Individual-level factors	• Examples of direct communication between decision-makers and communities addressing vaccine concerns which impacting community's decision to vaccinate themselves or their children.

Table 3: Exhaustive list of nodes describing conceptualization and support for community engagement for introduction and uptake of new and emerging vaccines in India, 2018.

Conceptualization of Community Engagement	
1a. Egalitarian	Perceiving communities as equal partners and leaders by vaccine policymakers.
1b. Evaluative definition of CE	Opinion based comment on virtue of community engagement leading to vaccination uptake.
1c. Ideal normative definition examples of CE	Ideal definition of what community engagement should be, irrespective of what the organization is doing or not doing. Defining ideal community engagement processes which will lead to community engagement (goal).
1d. Organizational interventions with or for CE	The actual programmatic interventions with/at community-levels by the organization for vaccination uptake.
(i) Community empowering interventions	Processes leading to empowered communities.
(ii) Personal narratives	What the respondent did in her/his current or earlier position to engage the communities. Mostly use of first person
(iii) Token interventions	Roger Hart's Ladder of Participation which defines this as the lowest level of community engagement.
(iv) Top-down interventions	Vertical program delivery and perception of community as beneficiaries, rather than equal stakeholders to vaccination program.
▪ Communication and capacity building interventions	Inter Personal Communication (IPC), Information Education and Communication (IEC), Behavior Change Communication (BCC), mass-media messaging for sensitization and awareness and capacity building trainings of workers, peer educators, health care workers and local stakeholders.
▪ Supply chain management	Ensuring supply of vaccines from the center to the ground levels.
(v) Transactional interventions	Dialogue with the community to build faith, trust and credibility for policymaker's/vaccine delivering system.
(vi) Vaccination delivery by frontline HCWs	Vaccination delivery by frontline healthcare workers (HCW) to vaccine eligible population.
Evolution of definition of Community Engagement	
2a. Comparing	Comparing different vaccine delivery/CE strategies across time or different vaccines, or comparing vaccination with other programs, urban and rural differences in delivery strategies and how things were/are done in other countries.
2b. Evidence base scientific approach	Learning from one vaccine experience, presence or lack of evidence/data/indicators of CE in the vaccine arena.
2c. Institutional strategic orientation	Organizational learnings and strategic orientations and shifts over time, across different vaccines and on the issue of community engagement in the vaccine space.
2d. Opinion based	Ideal opinions, more of rhetoric questions if that would work.
2e. Personal narrative	How his/her own conceptualization/role to engage with communities has changed over the years, in this and earlier organizations.
2f. Transformative	Macro transformations based on the burden of disease, vaccine availability like progressive state (HPV in Punjab) etc. Policymakers' thoughts to initiate new methods/models/strategies.

Support to promote Community Engagement	
3a. Global stakeholders	Support/help/solidarity of global partners and donors.
3b. Ideal or evidence of other regions or institutions	Support/help/solidarity of global partners and donors, or international collaborations of technical think tanks.
3c. National stakeholders	Support/help/partnership/solidarity of national-level organizations and national-level vaccine ambassadors or advocates. Political will of the Ministry/Prime Minister/Chief Minister.
3d. Respondent's own organization	Acknowledging enabling environment in the organization and support of the organizational head.
3e. Self	
(i) Duty	Performing his/her duty.
(ii) Responsibility	Self-motivated and performs beyond stipulated duty for innovative CE strategies.
Resources for Community Engagement in the Organization	
4a. Financial resources	Monetary resources within the organization which they have, or lack of finances.
4b. Human Resources	Human resources within the organization, e.g. Community outreach capacity of the organization - which they have or lack and should ideally possess.
Partnerships for Community Engagement	
5a. With global entities	Partnership with global organizations/and donors.
5b. With national organizations/technical bodies	Partnership with local organizations/technical body of the ministry/higher education institutions.
5c. With local CBOs, CSOs, Youth Clubs, communities etc.	Partnership with local CBOs, CSOs, Youth Clubs, communities etc.
5d. Partnerships at organizational-level	Ideal partnerships which would be helpful.
5e. Organizational	Existing partnerships of the organization/institution.
Community-level Enablers for Community Engagement	
6a. Local level influencers	Religious leaders, clubs, women's groups who influence positive vaccination decision among communities.
6b. Disease outbreaks	Certain outbreaks which compelled parents vaccinating their children.
Community-level Barriers for Community Engagement	
7a. Demand side barriers	
(i) Access	Child sick or travelling or nobody at home to take the child to the vaccination site.
(ii) Blackmailing and strategizing	Communities strategizing with Govt due to lack of trust – like 'build the road then we will take the vaccines' or 'what must be the plot of the Govt. to vaccinate' etc.
(iii) Fear and reluctance	Fear of illness or of death of child, fear of religious incompetence due to vaccination, arising from experience with this child, another child, neighbor's child or media reports.
(iv) Lack of information	No knowledge about vaccines, no knowledge of vaccine schedules and lack of information about importance of the vaccines

(v) Myths and Rumors	Spreading of misinformation
(vi) Power-structures in the society	Structural barriers related to class, caste, and gender, rural versus urban hindering reach of marginalized communities to getting vaccinated.
7b. Supply side barriers	
(i) Access	Health care worker not present in the session site, vaccines not there, vaccines there but have crossed the due date, vaccines could not reach the under-reached/under-served areas.
(ii) Power-structures in the society	Structural barriers like power relations between researcher and community in the society, hindering reach of marginalized communities to getting vaccinated.

Table 4: Profile of vaccine decision-makers in India who participated in this study, 2018

Study participant	**Academic background** *(Basic science and research = Basic Science; Public Health/Community Medicine/, Humanities/Management = Humanities/ Public Health)*	**Category of organization of employment** *(Govt. of India=GOI, Technical body of the GOI = Technical body, UN organization, Donor organization = Donor, National-level NGOs with policy influencing and vaccine roll out role = NGOs (Policy influencing), International /National-level NGOs with vaccine research and roll out role = NGOs (Research, roll-out, advocacy)*	**Governance levels** *MoHFW= Ministry, State-level nodal institutions of the Ministry = State nodal office, Technical consortium under the aegis of the Ministry= Technical consortium, HQ in a developed country with country office in India = Country office in India, Principal financial recipient from a foreign donor and programmatic ownership of Govt. of India = Principal recipient projects, NGOs with an India office)*	**Organizational role for community engagement** *(Establish regulations = Regulatory, Carry out surveillance/research= Surveillance/research, Provide funding = Financial support, Develop policy guidelines/technical support = Technical support, Develop communication strategies and materials= Communication strategies, Implement nationally sanctioned policies and programs = Policy and program implementation)*	**Leadership's level of decision making** *(Asia-Pacific region, National-level, State-level)*
1.	Basic Science	GOI	Ministry	Regulatory	National-level
2.	Basic Science	GOI	Ministry	Regulatory	National-level
3.	Basic Science	GOI	State nodal organization	Policy and program implementation	State-level
4.	Humanities& Public Health	GOI	State nodal organization	Policy and program implementation	National-level
5.	Basic Science	GOI	State nodal organization	Policy and program implementation	National-level (Retired)

6.	Basic Science	Technical body, GOI	Technical consortium	Technical support	National-level
7.	Basic Science	Technical body, GOI	Ministry	Policy and program implementation	National-level
8.	Basic Science	GOI	Ministry	Regulatory	National-level
9.	Basic Science	GOI	Ministry	Regulatory	National-level
10.	Basic Science	UN organization	Country office in India	Regulatory and Surveillance/research	Asia-Pacific region
11.	Basic Science	UN organization	Country office in India	Technical support and Communication strategies	Asia-Pacific region
12.	Basic Science	UN organization	Country office in India	Regulatory	Asia-Pacific region
13.	Basic Science	Donor	Country office in India	Financial support & Technical support	National-level
14.	Basic Science	Donor	Country office in India	Financial support & Technical support	National-level
15.	Basic Science	Donor	Country office in India	Financial support	National-level
16.	Basic Science	NGOs (Policy influencing)	Principal recipient projects	Communication strategies & Policy and program implementation	National-level
17.	Basic Science	NGOs (Policy influencing)	Principal recipient projects	Communication strategies & Policy and program implementation	National-level
18.	Basic Science	NGOs (Policy influencing)	Principal recipient projects	Communication strategies & Policy and program implementation	State-level
19.	Humanities/ Public Health	NGOs (Policy influencing)	Principal recipient projects	Communication strategies & Policy and	National-level

				program implementation	
20.	Humanities/ Public Health	NGOs (Research, roll-out, advocacy)	NGOs with India office only	Surveillance/research & Technical support	Asia-Pacific region
21.	Basic Science	NGOs (Research, roll-out, advocacy)	NGOs with India office only	Surveillance/research & Technical support	Asia-Pacific region
22.	Basic Science	NGOs (Research, roll-out, advocacy)	Country office in India	Regulatory & Surveillance/research	Asia-Pacific region
23.	Basic Science	NGOs (Research, roll-out, advocacy)	Country office in India	Surveillance/research & Technical support	National-level
24.	Humanities/ Public Health	NGOs (Research, roll-out, advocacy)	Country office in India	Policy and program implementation	National-level
25.	Science	NGOs (Research, roll-out, advocacy)	Country office in India	Policy and program implementation	National-level

Table 5: Epistemological categorization of communities by vaccine decision-makers in India, 2018

Categorization of communities	Constituting populations
Priority populations	• Parents of vaccine eligible children and young persons • Vaccine eligible populations who demanded vaccines • Key populations participating or potential participants to vaccine clinical trials
Gatekeepers	• Vaccine resistant populations • Husbands and mother-in-laws minority communities • Anti-vaccine lobbyists • Activists
Local stakeholders	• Frontline healthcare workers, • Members of local CBOs, clubs, SHGs • Members of local technical bodies • Bodies of local governance
Unclear whether communities or not	• NGOs • Media

Table 6: Broad categorization of ownership and fostering of CE by vaccine decision-makers in India, 2018

	Categorization of ownership and fostering of CE by vaccine decision-makers	Exemplars
1.	CE as a community empowering role	*"Some journalist misinterpreted and had adverse reports. Honestly, we didn't get that much support from authorities in my headquarters but my CAB met within few days and went ahead and said that we are willing to give out rejoinder to this news report because we know you have been very very meticulous about protecting the individuals, have been transparent and sensitive to community."*
2.	CE as vaccine delivery with the help of frontline workers	*"I always appreciate my workers. The hard work that our ANMs and field staff are putting in in is tremendous. So if we have coverage of 90%, it is not my contribution, it is all because of my field workers who are doing a great job"*
3.	CE as a part of the organizational structure	*"There was the country and the regional programs where there was advocacy efforts to engage the community. There was a representative in the senior management team from the CRP. Representatives of the Board of Directors, who in one capacity or the other were the advocates of the community."*
4.	CE as a proactive social and altruistic responsibility	*"I remember there were two places in Tripura where the vaccines was transported through helicopter. First time Government of India gave that fund. Although the beneficiary children were only 15 I argued that if 100% children are to be immunized you have to somehow send the vaccines to this remote place. Else, it will take 7-8 days to reach there."*
5.	CE to comply to GOI and/or global mandates	*"Since we did not have any great experience in vaccine trial and community engagement it* (CE) *was introduced to us through our sponsors and collaborators like National Institute of Health"*
6.	CE as a duty delegated to the States and lower offices	*"No no, we do not do that part. Government of India does not run the programs at the peripheral levels."*
7.	CE as vaccine imposition/delivery	*"When children were dying and JE vaccine was introduced, people were fighting to get the vaccine. There was a firing in three places. People got a notion that if the vaccine stocks were finished we will go and their child will not get vaccinated, and so the rush and the panic 'me first' 'me first."*

Table 7: Overview of vaccines policy documents in India reviewed in this study, 2018

Document type (N=24)	**Title**	**Publication year**	**Publishing authority**
Policy and Program review documents (3)	• National Vaccine Policy	2011	MoHFW, GoI
	• Midterm Review Multi-Year Strategic Plan 2013-17	2016	MoHFW, and NHM, GoI
	• Universal Immunization Program Reaching Every Child 2013-17		MoHFW, GoI
Vaccine and program specific operational guidelines (7)	• Mission Indradhanush, Operational Guidelines	2015	NHM, GoI
	• Intensified Mission Indradhanush (IMI), Operational Guidelines	2018	MoHFW, and NHM, GoI
	• Operational Guide Japanese Encephalitis Vaccination in India	2012	NHRM, GoI
	• Introduction of Measles – Rubella Vaccines, Campaign and Routine Immunization	2017	MoHFW, and NHM, GoI
	• Operational Guidelines for Introduction of Inactivated Poliovirus Vaccine (IPV)	2015	MoHFW, and NHM, GoI
	• Operational Guidelines Introduction of Rotavirus Vaccine in the Universal Immunization Programme in India	2015	MoHFW, and NHM, GoI
	• Operational Guidelines, Pentavalent Introduction (DPT+HepB+Hib)	2014	MoHFW, and NHM, GoI
FAQ booklets for communities (3)	• FAQ on Immunization For Parents & Caregivers	2017	MoHFW, and NHM, GoI
	• FAQ on Immunization, for Health Workers & Other Front-line Functionaries	2017	MoHFW, and NHM, GoI
	• FAQ on Immunization for Religious Leaders, Media Persons, CSOs, Influencers & Other Stakeholders	2017	MoHFW, and NHM, GoI
AEFI related documents (3)	• AEFI Media Communication Protocol		ITSU and NHM, GoI
	• AEFI Surveillance and Response Operational Guidelines	2015	MoHFW, and NHM, GoI

	• National Quality Assurance Standards for AEFI Surveillance Program	2016	MoHFW, and NHM, GoI
Communication and Social mobilization related documents (8)	• Social Mobilization, Lessons from the Core Group Polio Project in India,	2012	USAID and CORE Group
	• Intensification of Routine Immunization Communication Operational and Technical Guideline	2012	NRHM, and MoHFW, GoI
	• Evaluation of Social Mobilization Network, Final Report Main Section	2014	UNICEF
	• GAVI UNICEF Alliance Partnership Document with India	2015	GAVI
	• CORE India Communication Strategy	2017-2022	CORE India
	• Standard Operating Procedures for engaging with youth institutions for social mobilization for IMI and RI	2018 2013	MoHFW, and Rotary International India National Polio Plus Committee
	• Communication Guidelines for Building Vaccine Confidence around AEFI	2016	NRHM, and MoHFW, GoI
	• Communication Guidelines for Building Vaccine Confidence around AEFI		MoHFW, GOI, WHO, UNICEF and Rotary International India National Polio Plus Committee

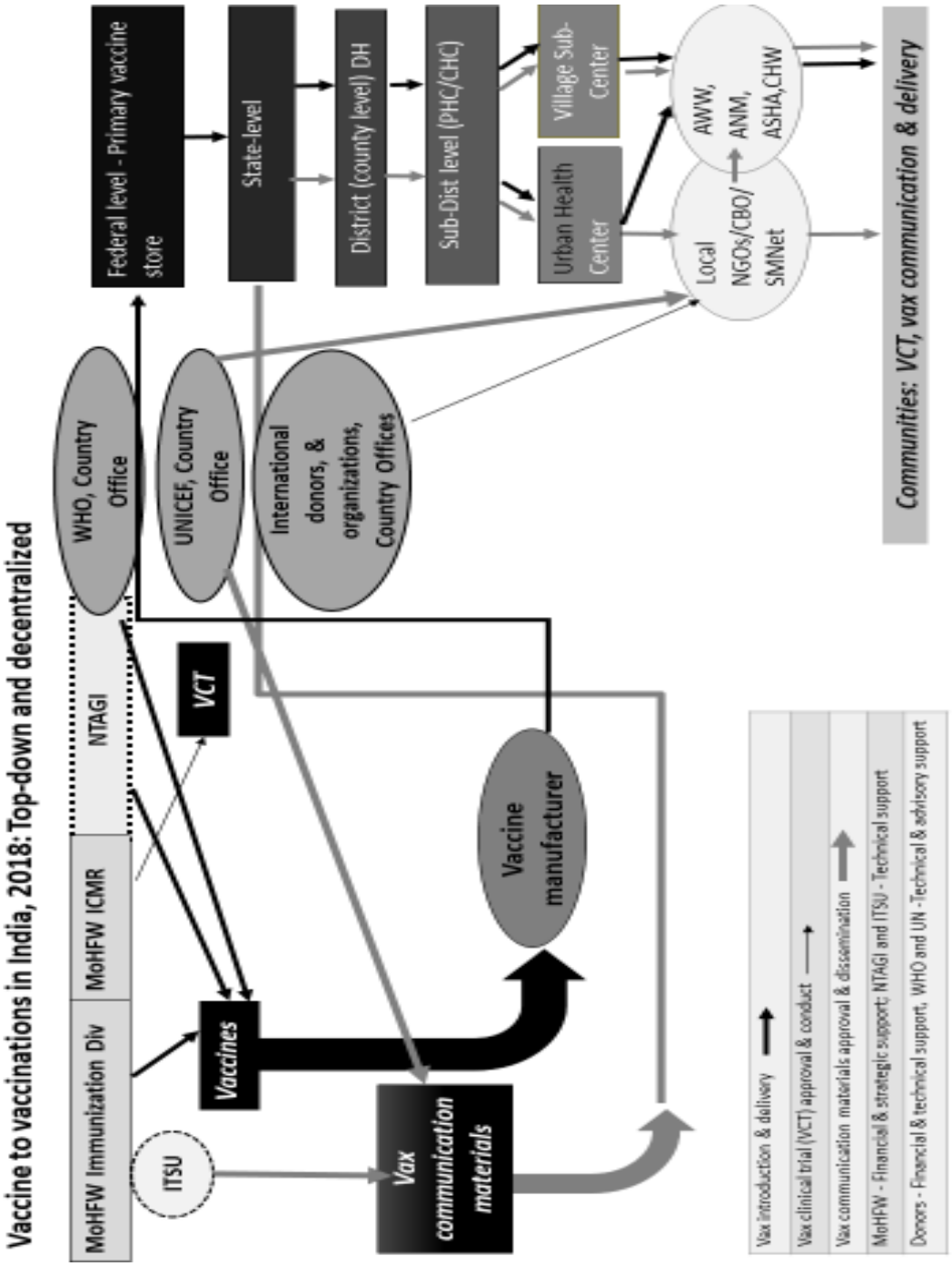
FAQ: Frequently Asked Questions, ITSU: Immunization Technical Support Unit, GoI: Government of India, MoHFW: Ministry of Health and Family Welfare, NHM: National Health Mission, NRHM: National Rural Health Mission, MoHFW, GoI, GAVI: The vaccine Alliance, UNICEF: United Nations International Children's Emergency Fund, USAID: United States Agency for International Development, WHO: World Health Organization

Table 8: Summary of Community Engagement (CE) Enablers and Barriers for Vaccination in India reported by National Decision-makers and Policy Documents by Levels of Socio-Ecological Model, 2018

SEM Levels	CE facilitators	CE barriers
Policy-level factors	• Evidence of political-will for CE. • Evidence of direct communication between decision-makers and communities addressing vaccination related inquiries	• Predominantly social mobilization approach, rather than CE • Adhoc CE interventions during AEFIs or any other emergency • Lack of any CE indicator • Lack of CE policy/strategy document • Lack of village level communication plan
Community-level factors	• Publication and dissemination of targeted SBCC materials	• Evidence of class, caste, gender, rural versus urban related power-structures in communities • Skewed power relations between communities and health staff or vaccinating authorities • Top-down power relations between NGOs and Government/donors • Lack of sub-population specific SBCC materials • Lack of family-centric strategies to promote consultative household level vaccination decision making • Lack of evidence in policy documents highlighting power relations between stakeholders
Organizational-level factors	• Evidence of formal partnerships between national and local stakeholders (religious leaders, clubs, women's groups)	• Lack of formalization of partnerships between national and local stakeholders (religious leaders, clubs, women's groups) • Lack of evidence of partnership aiming to strengthening CE • Lack of quality investment in understanding community sentiment and tailoring trainings and SBCC materials accordingly • Lack of consistent strategic planning or policy guideline for contested vaccines

Interpersonal-level factors	• Evidence of evolution of sensitive messaging in vaccination related IPC and SBCC documents • MI logo • Evidence of utilization of social media as much as traditional media for SBCC • Tailored SBCC with men and mothers in law, considering the patriarchal setting in India	• Lack of any mention of social-media proliferation in policy documents • FAQ documents, irrespective of the target group had the same language and presentation • No evidence of replicating SBCC interventions during Polio campaigns for new vaccines • Complex language in AEFI documents • Decision-makers did not take ownership of contested vaccines or any AEFIs • Lack of rumor management strategies
Individual-level factors		• Non-vaccination or lack of CE was mostly positioned as the community's fault • Use of physical power to manipulate vaccination decisions

Figure 1:



Source: Adapted from the Handbook for Vaccine & Cold Chain Handlers Mininstry of Health and Family Welfare, India 2015

ANM - Auxiliary Nurse and Midwife; ASHA - Accredited Social Health Activists; AWW - Anganwadi Worker; MoHFW - Ministry of Health and Family Welfare; ITSU - The Immunization Technical Support Unit; MoHFW - Ministry of Health and Family Welfare NTAGI - National Technical Advisory Group on Immunization in India; SMNet - Social Mobilization Network; UNICEF - United Nations Children's Fund; WHO - World Health Organization

Figure 2: Visual depiction of multi-staged and concurrent qualitative study design to examine community engagement in vaccine policies and programs in India, 2018

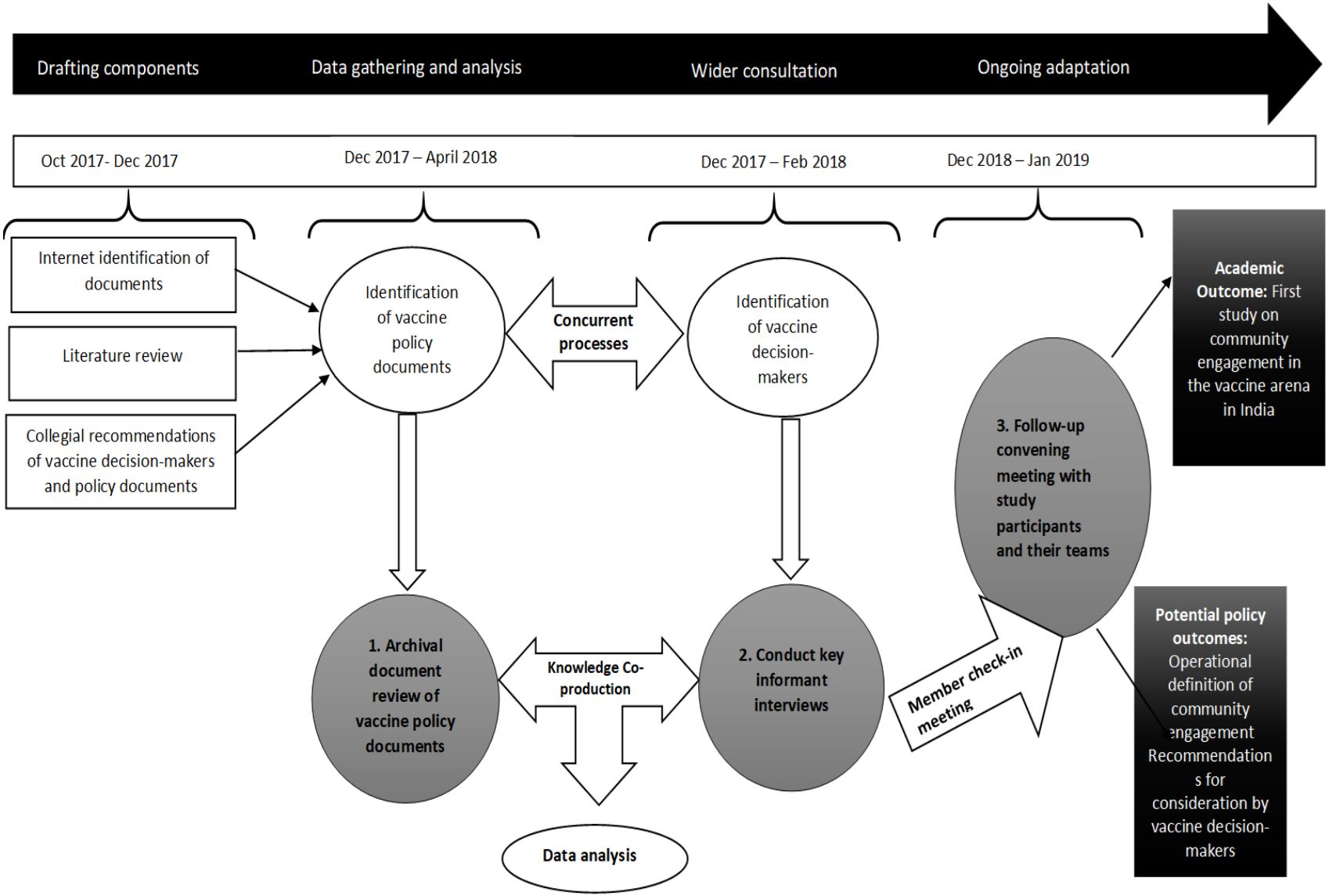
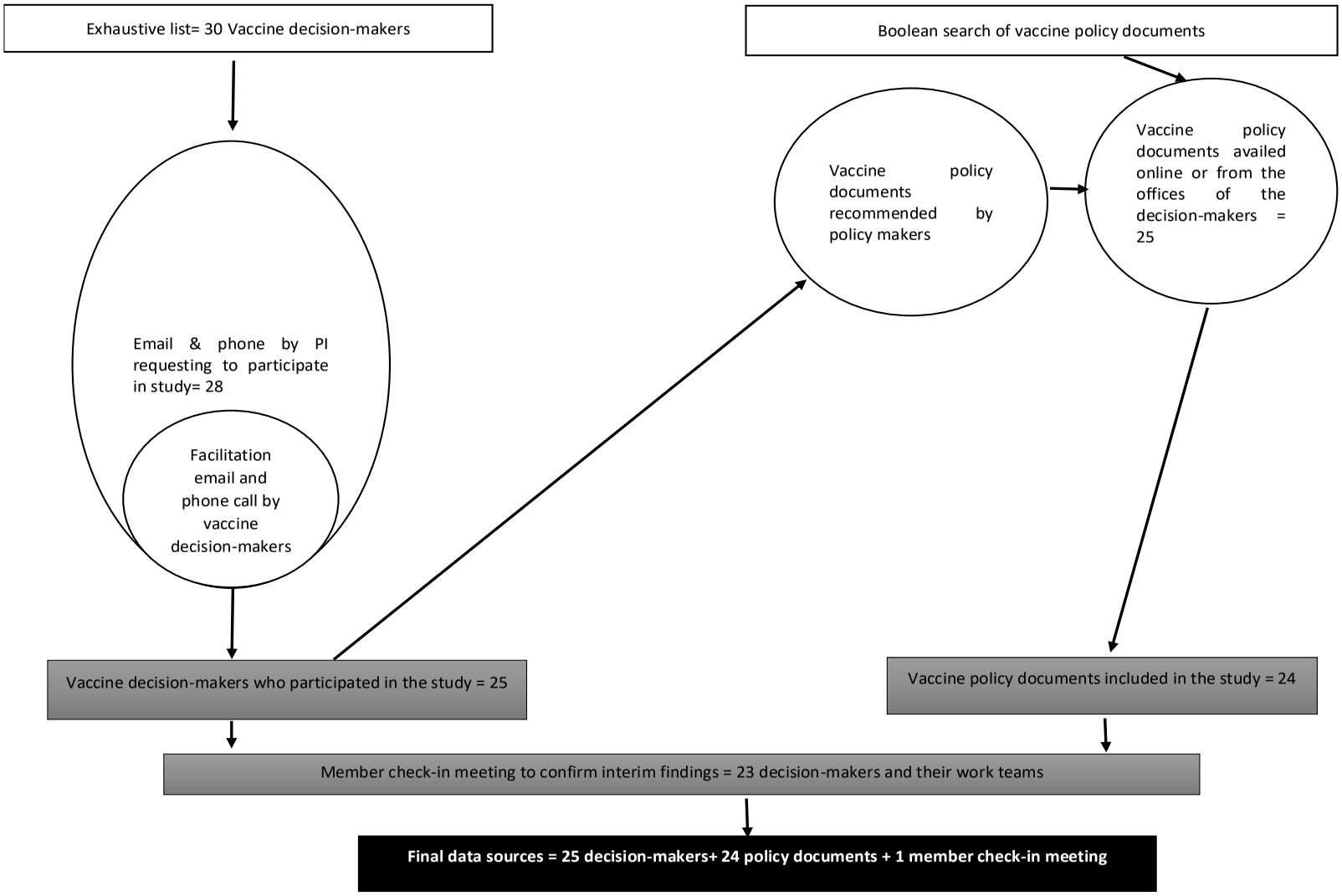


Figure 3: Multi-strategy inclusion model and data sources to examine community engagement in vaccine policies and programs in India, 2018



APPENDIX A: ABBREVIATIONS

AEFI	Adverse Event Following Immunization
ASHA	Accredited Social Health Activists
ANM	Auxiliary Nurse and Midwives
AWC	Anganwadi Center
AWW	Anganwadi Worker
BCC	Behavior Change Communication
BCG	Bacille Calmette-Guerin vaccine
BRIDGE	Boosting Routine Immunization Demand Generation
C4D	Communication for Development
CBO	Community Based Organization
CDC	Center for Disease Prevention and Control
CE	Community engagement
CHW	Community Health Worker
CGPP	CORE Group Polio Project
CSO	Civil Society Organization
DPT	Class of combination vaccines against three infectious diseases in humans: diphtheria, pertussis, and tetanus
EPI	Expanded Programme on Immunization
GAVI	Gavi, the Vaccine Alliance
GoI	Government of India
GVAP	Global Vaccine Action Plan 2011-2020
HPV	Human Papillomavirus
IAP	Indian Academy of Pediatrics
IAVI	International AIDS Vaccine Initiative
ICGEB	International Centre for Genetic Engineering and Biotechnology
IEC	Information Education Communication
IMI	Intensified Mission Indradhanush
IPC	Interpersonal Communication
ITSU	Immunization Technical Support Unit
KFT	Knowledge Flow Theory
LMIC	Low and Middle Income Countries
MoHFW	Ministry of Health and Family Welfare, India
MI	Mission Indradhanush
M-R	measles and rubella virus vaccine
MOU	Memorandum of Understanding
MSG	Mission Steering Group
NCR	National Capital Region
NGO	Non-Governmental Organization
NIH	National Institutes of Health
NTAGI	National Technical Advisory Group on Immunisation in India
NCC	National Cadet Corps

NHM	National Health Mission
NPSP	National Polio Surveillance Project
NSS	National Service Scheme
NYK	Nehru Yuvak Kendra
PDS	Public Distribution System
SBCC	Social Behavior Change Communication
SEM	Social Ecological Model
SHG	Self Help Group
SMNet	Social Mobilization Network
SC	Scheduled Caste
SOP	Standard Operating Procedure
ST	Scheduled Tribe
ToT	Trainin g of Trainers
UNICEF	United Nations Children's Fund
UIP	Universal Immunization Program
VHND	Village Health and Nutrition Day
WHO	World Health Organization

APPENDIX B: DEFINITION OF STUDY TERMS

'Community' refers to define vaccine user communities. Specifically, this will include: 1) parents of vaccine eligible children, who have a surrogate vaccination decision-making role; pregnant women, adolescent children and other adults eligible for certain adult vaccines, who have a joint or individual vaccine decision-making role and those who might be in different risk-benefit profiles who utilize or are potential users of vaccines provided through the Government's immunization programs, available for free. It will also include 2) community based organizations (CBOs), parents' teachers' associations, mother-in-law and daughter-in-law dyads, Community Advisory Boards (CABs), adolescent health focused groups like *Kishori Panchayats* and the likes working towards improving vaccination utilization among the vaccine eligible and potential user communities.

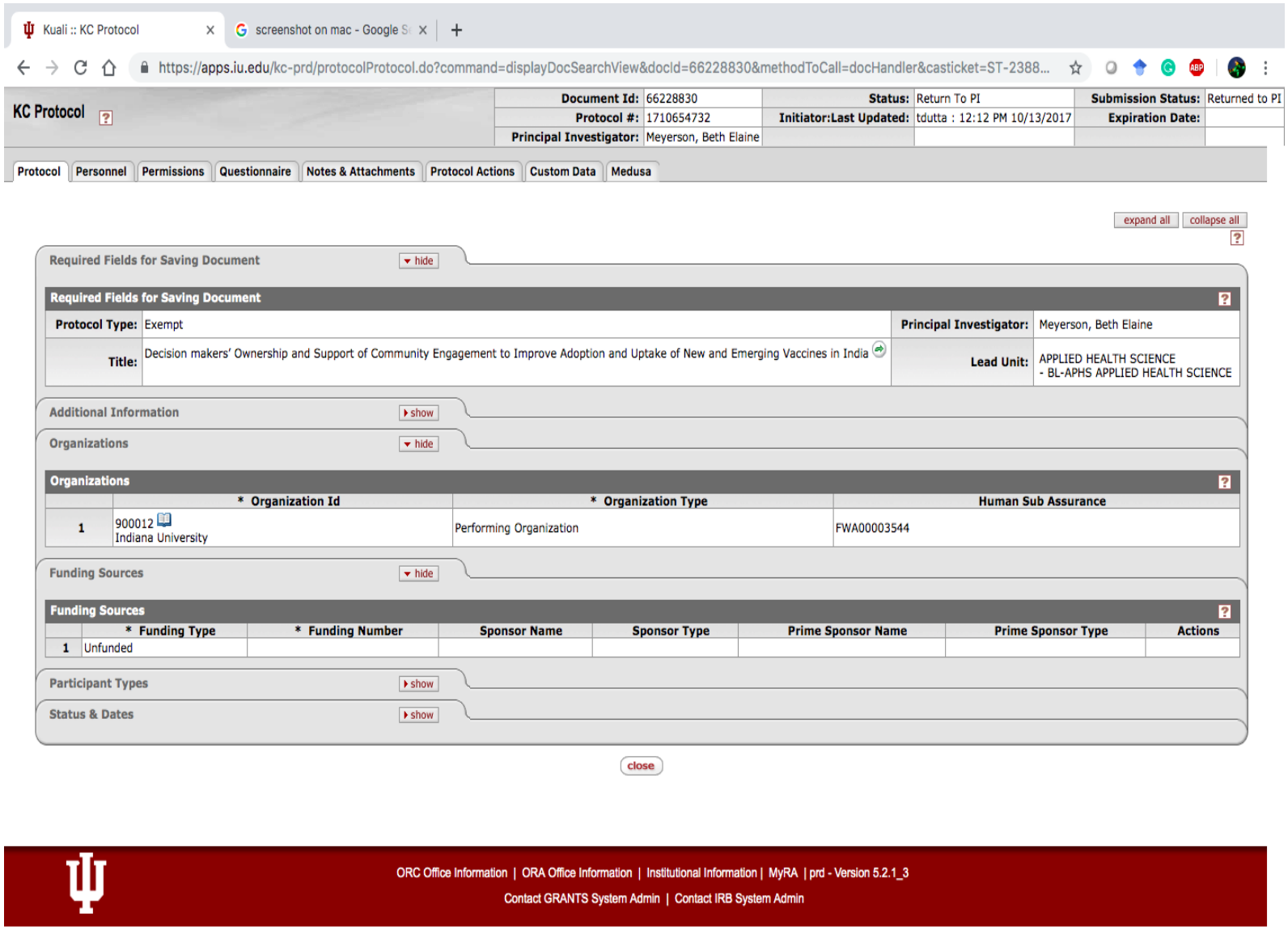
'Community engagement' refers to efforts by people with vaccine policy standing in India to 'involve', 'consult' and 'collaborate' with community members and community stakeholders as self-determining actors in ways that lead to their own understanding and uptake of strategies and actions to improve their vaccination decisions for themselves and their children. Here I have also examined if community engagement is just with the motive to increase vaccine demand generation or increased participation in government run vaccination campaigns, or is there any evidence of a fundamental shift in how the government perceives communities and works with them. We will also see if the communities engaged in the longer run will become more responsive to immunizations, especially in the case of new vaccines. The study would not visualize

this shift as a revolution, but rather as a sustainable and incremental evolution process based on the externalities, existing circumstances, and allowing community agency to mature and develop.

'Community-level/Based Organizations' (CBOs) are formal or informal institutions like women's SHGs, with public health functions, who are located in the community, and are both socially and/or spatially defined with particular shared characteristics (such as geographic location, cultural practices, beliefs etcetera). These CBOs consists of different members of the community who are members of these institutions based on self-identification and/or external attribution.

'Vaccine decision-makers' or **'elites'**, are persons who have been in positions of authority (>7-10 years) and have been responsible for formulating and approving the vaccine policy, vaccine specific guidelines, and programs in India, have signed off the introduction and roll out of vaccines under the UIP, have played decisive roles in improving vaccine related communication in all vaccine related Social and Behavior Change (SBCC) materials, and few who have led vaccine clinical trials between 2010 to current times. Most of them have also been part of vaccine ethics committees, and other advisory technical groups in India, or the Asia Pacific regions. These institutions/agencies the elites work could be classified into five broad kinds: National-level Ministries and Departments of the Government of India, technical advisory groups, UN agencies, donors, and international development organizations.

'Vaccine policy documents' refers to any national-level vaccine policies, vaccine strategy documents, Frequently Asked Question documents on vaccines for different stakeholders, Adverse Event Following Immunization, and vaccine specific guideline documents in India. These documents address immunization goals, and sensitize stakeholders and communities on vaccination gains. They are jointly published by the MoHFW and the National Health Mission (NHM), country offices of the World Health Organization (WHO), United Nations International Children's Emergency Fund (UNICEF), and/or the CORE Group Polio Project (CGPP), during 2010 to current times. Accordingly, most of these vaccine policy documents were either available on the website of the Ministry, or the National Technical Advisory Group on Immunization (NTAGI), or the Immunization Technical Support Unit (ITSU). While all the documents were available both in English (the official/professional language mostly practiced in India) and Hindi (the constitutionally approved national and official language of India), only the English version of these vaccine policy documents were included and reviewed in this study.



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KC Protocol

Document Id:	66228830	**Status:**	Return To PI	**Submission Status:**	Returned to PI
Protocol #:	1710654732	**Initiator:Last Updated:**	tdutta : 12:12 PM 10/13/2017	**Expiration Date:**	
Principal Investigator:	Meyerson, Beth Elaine				

Protocol | Personnel | Permissions | Questionnaire | Notes & Attachments | Protocol Actions | Custom Data | Medusa

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Protocol Type:	Exempt	**Principal Investigator:**	Meyerson, Beth Elaine
Title:	Decision makers' Ownership and Support of Community Engagement to Improve Adoption and Uptake of New and Emerging Vaccines in India	**Lead Unit:**	APPLIED HEALTH SCIENCE - BL-APHS APPLIED HEALTH SCIENCE

Additional Information — show

Organizations — hide

Organizations

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Funding Sources

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Participant Types — show

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Contact GRANTS System Admin | Contact IRB System Admin

APPENDIX D: (1) KEY INFORMANT INTERVIEW GUIDE

Introduction

I am Tapati Dutta, a doctoral candidate at the school of public health at Indiana University-Bloomington, U.S.A. Thank you for taking time to participate in this study. As you already know, this is for my doctoral research. I hope you received the information sheet about the study. Have you had a chance to review this?
If yes, do you have any questions about this study? [Pause to discuss questions]
If no, please take a moment to review this information (give information sheet. After review): Do you have any questions about this study? [Pause to discuss questions]

Now that you have reviewed and discussed the study information, will you agree to participate in this interview?
If no, we conclude the interview with thanks.
If yes, May I begin and start the recording?

[Start the recording]

Part I: Understanding community engagement
1. Briefly describe your institution's history with community engagement to improve vaccination uptake in India since 2010.

a. [Probe]: With which/what communities or groups does your agency tend to work?
b. [Probe]: Please describe this relationship with the abovementioned community group/s.
c. [Probe]: How was this relationship formed
d. [Probe]: How has your agency/institution engaged communities in vaccine decisions?

2. In your opinion, how does your agency/institution define community engagement?

a. [Probe]: How are the values of outreach and engagement reflected in your institutional mission statement and/or strategic plan, institution's structure and governance?
b. [Probe]: How is this similar or different from your own views?
c. [Probe]: How has this changed over time?
d. [Probe]: Is this the same across vaccines?

3. How would you think the leader or senior management in your agency/institution supported advancing community engagement for vaccines?

a. [Probe]: Can you give some examples that characterize leadership strategies and activities to advance outreach and engagement at national, state and local levels?
b. [Probe]: Would you also like to mention if there are any example since 2010 where community engagement has not been supported [appropriately] and how the leadership in your agency/institution, addressed it?

4. In what ways does your agency/institution partner with private sector, NGOs, communities and media to support and advance community engagement for vaccination acceptance and uptake?

a. [Probe]: Are these partnerships institutionally driven, or are they driven by a few leaders?
b. [Probe]: Who do you think are the leaders, advocates and gate-keepers in community outreach and engagement who are not formally charged but who are highly visible? Can you give me some examples?

Part II: Understanding the enablers and barriers of community engagement for vaccine introduction and uptake
Please describe the financial resources and trained human resources at all levels in your agency/institution to advance community engagement for vaccines?

a. [Probe]: What are the key financial and human resources for effective community engagement?
b. [Probe]: What would you think as key barriers for adequate financial and human resources for effective community engagement?

What are your thoughts on communities' level enablers to promote community engagement, especially for new and emerging vaccines?

[Probe]: Please give some examples

What are your thoughts on communities' level myths and misconceptions which are or could be barriers to community engagement for new and emerging vaccines?

[Probe]: Please give some examples

[Probe]: Please give examples of social messaging, community sensitization, community mobilization to address such misinformation and build community's trust for the vaccine delivery system and for new and emerging vaccines

In your opinion what more can your agency/institution do to build a more enabling environment within your agency/institution to advance community engagement in vaccine introduction and delivery?

[Probe]: Please give some examples

Any additional comments?
If yes [interview will continue]
If no:

We have completed the interview. Thank you for your time and the information which you provided. Once the study is completed, I will share the findings with you once we have published them.

In the course of analysis, may I contact you briefly if I have additional questions about your comments?

Thanks again for your time. [Turn off the recorder].

End of interview

APPENDIX D: (2) COVER LETTER TO KEY INFORMANTS

Name
Title
Address
Via email

RE: Interview request for a study about community engagement in vaccine planning and policy

Dear Title [name],

I write to invite you to participate in a brief [30 minutes] interview to discuss your institution/agency's experience with and engagement of communities in vaccine policy and planning. This interview is part of my doctoral dissertation research on 'Decision-makers' Ownership and Support of Community Engagement to Improve Adoption and Uptake of New and Emerging Vaccines in India'. I have enclosed study information for your consideration. Dr. Beth Meyerson and Dr. Priscilla A. Barnes are the co-chairs of my dissertation committee.

India has made tremendous progress during our "Decade of Vaccines" (2010-2020) by introducing multiple new vaccines along with increasing access to new and underused vaccines. Despite our progress, vaccine uptake is less than it should be. Understanding community engagement in vaccine policy and planning may help to identify opportunities to further advance our vaccine efforts.
As a citizen of India, and a committed socio-behavioral scientist in community health, I have worked with Indian non-profit organizations for 15 years on issues of HIV and cervical cancer prevention as well as promoting use of prevention tools among the rural and vulnerable sub-populations of women and girls.

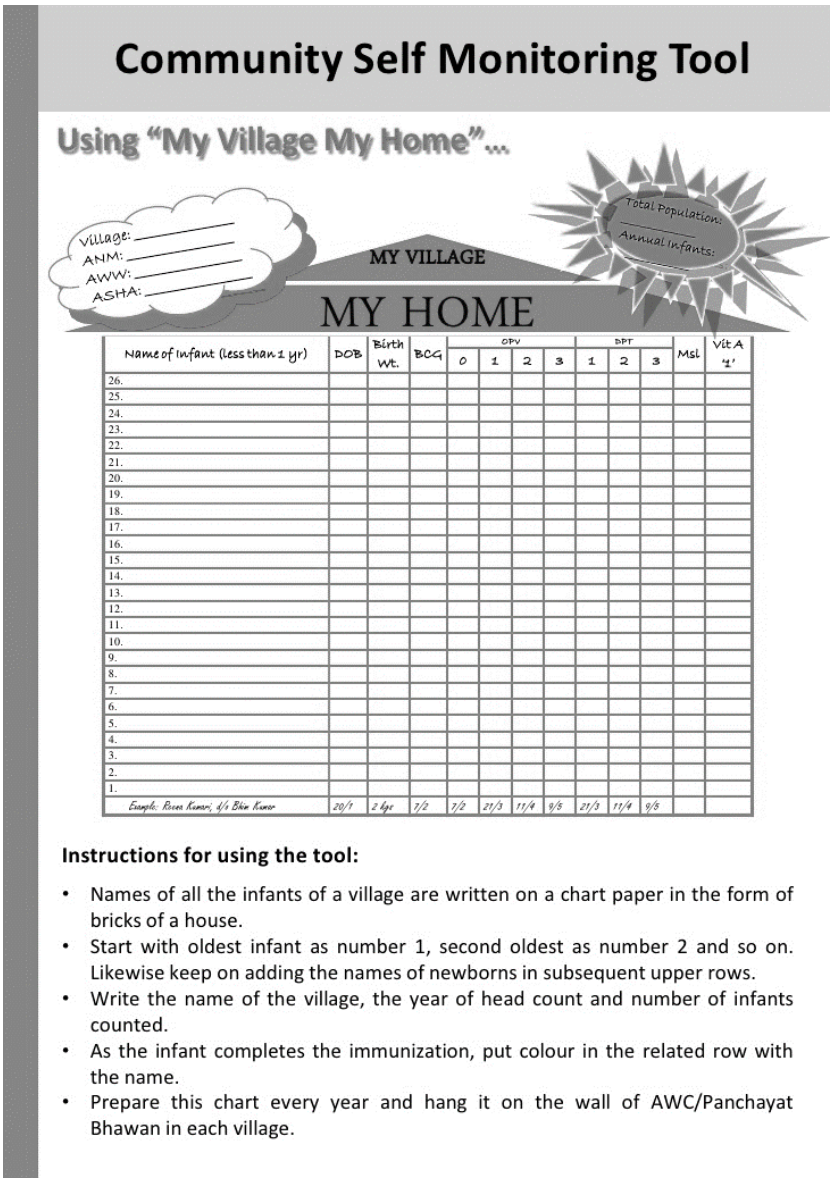
You are invited to participate in an interview because of your commendable vision and advocacy for vaccines in India. If you agree to participate in this study, please reply to this email and indicate your availability (dates/times) during this period: December 6, 2017- January 26, 2018. I will be in India during this time period, but can also arrange for an online/video interview if this is better for you.
I am hopeful for your decision to participate in a brief interview, and look forward to sharing the results of the study with you.

Sincerely

Tapati Dutta
Doctoral Candidate
Research Associate, Rural Center for AIDS/STD Prevention
Indiana University School of Public Health-Bloomington

APPENDIX E

My Village My Home, Published by MCIP with USAID support: Vaccination Monitoring Tool by the Community



Community Self Monitoring Tool

Using "My Village My Home"...

Village: _____
ANM: _____
AWW: _____
ASHA: _____

MY VILLAGE

Total Population: _____
Annual Infants: _____

MY HOME

Name of Infant (less than 1 yr)	DOB	Birth Wt.	BCG	OPV				DPT			MSL	Vit A '1'
				0	1	2	3	1	2	3		
26.												
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1.												
Example: Reena Kumari, d/o Bhim Kumar	20/1	2 kgs	7/2	7/2	21/3	11/4	9/5	21/3	11/4	9/5		

Instructions for using the tool:

- Names of all the infants of a village are written on a chart paper in the form of bricks of a house.
- Start with oldest infant as number 1, second oldest as number 2 and so on. Likewise keep on adding the names of newborns in subsequent upper rows.
- Write the name of the village, the year of head count and number of infants counted.
- As the infant completes the immunization, put colour in the related row with the name.
- Prepare this chart every year and hang it on the wall of AWC/Panchayat Bhawan in each village.